DOCTORAL THESIS

Towards shared decision making: exploring new ways of communicating evidence to patients about benefits and harms of antibiotics for acute respiratory infections.

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Towards shared decision making: exploring new ways of communicating evidence to patients about benefits and harms of antibiotics for acute respiratory infections

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Thesis Summary

Background

Acute respiratory infections (ARIs) are one of the most common reasons for consultations in primary care and receiving an antibiotic, despite good evidence that they confer only marginal benefit and that these benefits may be outweighed by harms, as well as the potential contribution to antibiotic resistance. Antibiotic resistance is the ability of bacteria to naturally adapt to antibiotics used to treat them and reduces their effectiveness, and is now a global threat to public health. Potentially modifiable factors contributing to primary care prescribing of antibiotics for ARIs include diagnostic uncertainty, perceived and expressed patient expectations for an antibiotic, and a clinician's desire to maintain patient satisfaction. Patients' misperceptions of antibiotic benefits and harms may also be a contributor to requests for antibiotics. These factors suggest a need to improve clinician and patient communication during consultations. Parents should be a particular focus, as children experience ARIs more frequently and are more likely to receive an antibiotic. With its focus on communication, discussing benefits and harms, and encouraging collaborative decision making, shared decision making may be an appropriate strategy for improving informed patient/parent choice about antibiotics for ARIs and reducing their use.

Aims

This thesis aimed to explore the appropriateness of using shared decision making to promote informed choice by patients as a strategy which may lead to reduced antibiotic use for ARIs in Australian primary care, with a particular focus on children.

Methods

Three interrelated studies were conducting to explore the appropriateness of shared decision making. Firstly, a systematic review and meta-analysis (Study 1) of studies evaluated the effectiveness of interventions which aimed to facilitate shared decision making about antibiotic use for ARIs in primary care. This was followed by a nation-wide survey (Study 2) which aimed to explore parents' beliefs and expectations about antibiotics for ARIs in children, and their preferred level of involvement in treatment decisions. Following this work, brief, evidence-based, patient decision aids for three common ARIs (acute otitis media, sore throat, and acute bronchitis) were developed. In the first stage of a multi-stage evaluation, a randomised trial (Study 3) was used to assess their effectiveness in preparing parents to make

an informed choice (a composite measure of decision quality: defined as adequate knowledge and consistency between attitudes and intention toward antibiotic use for a child's ARI) in a hypothetical scenario, and elicit parents' views about the acceptability and usability of materials.

Results

Key findings of the systematic review (Study 1) were that, compared with usual care, interventions which aimed to facilitate shared decision making reduced antibiotic prescribing for ARIs in primary care in the short term, without an increase in adverse clinical outcomes such as patient initiated re-consultations for the same illness, or decrease in patient satisfaction with the consultation. There was insufficient data to assess if the reduction in antibiotic use was sustained on the longer-term, or whether there was an increase in hospital admission, incidence of pneumonia, or mortality. No studies measured antibiotic resistance as an outcome. Multi-component interventions included were complex and intensive, limiting their use outside of the trial context and not suitable for use in Australian primary care. The nation-wide cross-sectional survey (Study 2) found most parents believed that antibiotics are necessary for common ARIs in children (particularly for acute otitis media), although many had misperceptions about why they are needed and how they can help. Parents over-estimated the benefits of antibiotics for reducing illness duration. Most parents also believed that antibiotics reduced the likelihood of illness-related complications. Many were aware of potential harms from antibiotics (including antibiotic resistance) although had inaccurate perceptions about some of these. Parents reported substantial use of over-the-counter and complementary and alternative medicines for symptom management. Less than half of parents recalled at least some discussion with their doctor about why antibiotics might be used. While it was reported that shared decision making occurrence was infrequent, nearly all parents wanted greater involvement in future decision making about antibiotic use for their child's ARI.

The randomised trial (Study 3) found that compared to the written information currently available to the Australian public, brief patient decision aids significantly improved parents' knowledge about antibiotic use in childhood ARIs, and enabled more parents to make an informed choice about whether to use an antibiotic for a child with a hypothetical future illness episode. However, the decision aids did not alter parents' attitudes towards antibiotic use, or intention to use antibiotics when their child has an ARI in the future. Parents liked the format and length of the decision aids, and their balanced content and visual presentation of antibiotic benefits and harms.

Conclusion and implications

Shared decision making appears to be an appropriate and effective strategy for improving parents' informed choice about antibiotic use for a child's ARI, and one that is desired by and acceptable to parents. Patient decision aids are a tool that can be used to facilitate the process of shared decision making and improve communication between clinicians and patients. This thesis has explored the appropriateness of shared decision making as a strategy to reduce unnecessary antibiotic prescribing for ARIs in primary care, and developed patient decision aids as a tool to assist its implementation. The research conducted as part of this thesis has answered a number of previously unknown questions and may lead to the reduction of antibiotic prescribing for ARIs in primary care.

Keywords

antibiotics; antibiotic resistance; acute respiratory infections; paediatrics; communication; decision aids; shared decision making; evidence-based practice

Declaration by candidate

This thesis is submitted to Bond University in fulfilment of the requirements of the degree of *Doctor of Philosophy by Published Work (PhD)*. This thesis represents my own original work towards this research degree, and contains no material which has been previously submitted for a degree or diploma at this University or any other institution, except where due acknowledgement is made.

Peter Dennis Coxeter 1/02/2018

Declaration of author contributions

Peter D. Coxeter is the sole author of Chapter 1 (General introduction), Chapter 2 (Literature review), Chapter 6 (Development of three brief patient decision aids about antibiotic use for acute otitis media, sore throat, and acute bronchitis), and Chapter 8 (Discussion). The remaining chapters (listed below) are co-authored publications on which Peter D. Coxeter was the lead author, with all other contributions acknowledged. The design, development and management of all studies, data collection and statistical analysis, drafting and revision of manuscripts, and reply to peer-reviewers, was the primary responsibility of the PhD candidate. Co-authors provided assistance with study planning and design, interpretation of data, and critical revision of the manuscripts. None of the work submitted in this thesis was carried out before the PhD candidature.

Co-authored publications

1. **Coxeter P**, Del Mar CB, Hoffmann TC. Preparing parents to make an informed choice about antibiotic use for common acute respiratory infections in children: a randomised trial of brief decision aids in a hypothetical scenario. *Patient*. 2017; 10(4):463-474.

2. **Coxeter P**, Del Mar CB, Hoffmann TC. Parents' expectations and experiences of antibiotics for acute respiratory infections in primary care. *Ann Fam Med.* 2017; 15(2):149-154.

3. **Coxeter P**, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. *Cochrane Database Syst Rev*. 2015; (11):CD010907.

4. **Coxeter P**, Looke D, Hoffmann T, Lowe J, Del Mar C. The antibiotic crisis: charting Australia's path towards least resistance. *Aust N Z J Public Health*. 2013; 37(5):403-404.

Statement of contributions

1. PC 75%, TH 15%, CDM 10%
2. PC 75%. TH 15%, CDM 10%
3. PC 70%, TH 10%, CDM 10%, LM 5%, EB 5%
4. PC 80%, DL 5%, TH 5%, JL 5%, CDM 5%

Research outputs arising from this thesis

Peer-reviewed publications

- **Coxeter P**, Del Mar CB, Hoffmann TC. Preparing parents to make an informed choice about antibiotic use for common acute respiratory infections in children: a randomised trial of brief decision aids in a hypothetical scenario. *Patient*. 2017; 10(4):463-474.

- **Coxeter P**, Del Mar CB, Hoffmann TC. Parents' expectations and experiences of antibiotics for acute respiratory infections in primary care. *Ann Fam Med.* 2017; 15(2):149-154.

- **Coxeter P**, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. *Cochrane Database Syst Rev*. 2015; (11):CD010907.

- **Coxeter P**, Looke D, Hoffmann T, Lowe J, Del Mar C. The antibiotic crisis: charting Australia's path towards least resistance. *Aust N Z J Public Health*. 2013; 37(5):403-404.

Peer-reviewed conference abstracts: oral presentations

- **Coxeter P**, Del Mar C, Hoffmann T. Helping parents make informed decisions about antibiotics for acute respiratory infections. Gold Coast Health and Medical Research Conference, Gold Coast, 30 November to 2 December, 2016.

- **Coxeter P**, Del Mar C, Hoffmann T. Helping parents to make informed decisions about antibiotic use for common acute respiratory infections in children: a randomised trial of brief decision aids. Higher Degree Research Conference, Faculty of Health Sciences and Medicine, Bond University, Gold Coast, 12 November, 2016.

- **Coxeter P**, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Interventions that facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. Gold Coast Health and Medical Research Conference, Gold Coast, 3 to 4 December, 2015.

Winner: "Best PhD/Honours Student Podium Award" and "Best of the Best Award".

- **Coxeter P**, Hoffmann T, Del Mar C. Parents' expectations of the benefit and harm of treatment for acute respiratory infections and views on shared decision making. Higher Degree Research Conference, Faculty of Health Sciences and Medicine, Bond University, Gold Coast, 18 November, 2015.

- **Coxeter P**, Hoffmann T, Del Mar C. Parents' expectations about the benefits and risks of treatment for acute respiratory infections in children and preferred level of involvement in management decisions. International Shared Decision Making (ISDM) and International Society for Evidence Based Health Care (ISEHC) conference, Sydney, 19 to 22 July, 2015.

- **Coxeter P**, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Shared decision making for acute respiratory infections in primary care: a Cochrane systematic review and meta-analysis. International Shared Decision Making (ISDM) and International Society for Evidence Based Health Care (ISEHC) conference, Sydney, 19 to 22 July, 2015.

- **Coxeter P**, Hoffmann T, Del Mar C. Exploring primary caregivers' expectations about the benefits and risks of treatment for acute respiratory infections in children and involvement in management decisions. Gold Coast Health and Medical Research Conference, Gold Coast, 4 to 5 December, 2014.

- **Coxeter P**, Hoffmann T, Del Mar C. Exploring primary caregivers' expectations about the benefits and risks of treatment for acute respiratory infections in children and involvement in management decisions. Primary Health Care Research Conference, Canberra, 23 to 25 July, 2014.

Peer-reviewed conference abstracts: posters

- **Coxeter P**, Del Mar C, Hoffmann T. Helping parents to make informed decisions about antibiotic use for common acute respiratory infections in children: a randomised trial of brief decision aids. Higher Degree Research Conference, Faculty of Health Sciences and Medicine, Bond University, Gold Coast, 12 November, 2016.

- **Coxeter P**, Hoffmann TC, McGregor L, Del Mar CB. Shared decision making for acute respiratory infections in primary care: a systematic review and meta-analysis. Primary Health Care Research Conference, Canberra, 23 to 25 July, 2014.

- **Coxeter P**, Hoffmann T, Del Mar C. Exploring primary caregivers' expectations about the benefits and risks of treatment for acute respiratory infections in children and involvement in management decisions. Primary Health Care Research Conference, Canberra, 23 to 25 July, 2014.

Ethics declaration

The research associated with Chapter 5 and Chapter 7 of this thesis received ethics approval from the Bond University Human Research Ethics Committee. Application ID/approval numbers, RO1744 and 15179, respectively.

Copyright declaration

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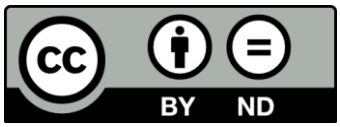

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experienced your beauty and courage in the 15 minutes we shared together - a humbling reminder that before God a child is yours to tender and not keep.

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Abbreviations

Abbreviations included only in tables within the thesis are excluded from this list, as they are described in footnotes below each table.

ACSQHC	Australian Commission on Safety and Quality in Health Care
AGAR	Australian Group on Antimicrobial Resistance
AMR	antimicrobial resistance
AMRPC	Australian Antimicrobial Resistance Prevention and Containment steering group
AMRSC	Antimicrobial Resistance Standing Committee
AOM	acute otitis media
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARI	acute respiratory Infection
ASTAG	Australian Strategic and Technical Advisory Group on antimicrobial resistance
AURA	Antimicrobial Use and Resistance in Australia project
CATI	computer assisted telephone interviewing
CDC	Centers for Disease Control and Prevention
CI	confidence interval
CIJIG	Commonwealth Interdepartmental JETACAR (*see below)* Implementation Group
CIPARS	Canadian Integrated Program for Antimicrobial Resistance Surveillance
COPD	chronic obstructive pulmonary disease
CRP	C-reactive protein
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry *(now the Department of Agriculture and Water Resources)*
DANMAP	Danish integrated antimicrobial resistance monitoring and research programme
DoHa	Australian Government Department of Health and Ageing *(now the Department of Health)*

EAGAR	Expert Advisory Group on Antimicrobial Resistance
GP	general practitioner *or* general practice
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	healthcare-associated infections
IPDAS	International Patient Decision Aids Standards
ITT	intention-to-treat
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
LRTI	lower respiratory tract infection
MD	Mean difference
NAUSP	National Antimicrobial Utilisation Surveillance Program
NHMRC	National Health and Medical Research Council
NNN	National Neisseria Network
NPS	National Prescribing Service
OR	odds ratio
PBS	Pharmaceutical Benefits Scheme
RaR	rate ratio
RCT	randomised controlled trial
RD	risk difference
RR	risk ratio
Strama	Swedish strategic programme against antibiotic resistance
TGA	Therapeutic Goods Administration
TSN	The Surveillance Network
UK	United Kingdom
USA/US	United States of America
WHO	World Health Organisation
WPA	Working Party on Antibiotics

Chapter 1

General Introduction

Background

Antibiotic resistance is an inevitable consequence of antibiotic use. Bacteria are able to develop resistance to antibiotics through natural adaptive processes,[1] and reduce the effectiveness of antibiotics. Global growth in the use of antibiotics has accelerated the development of antibiotic (including multi-drug) resistant pathogens.[2] The world has now entered a post-antibiotic epoch where some bacterial strains are no longer susceptible to all classes of antibiotics, with few new drugs being developed to replace them.[2] Antibiotic resistance increases treatment complexity and can result in treatment delay or failure.[1,2] Common infections may no longer be treatable, and halt routine surgical procedures or cancer chemotherapy requiring antibiotic cover.[2] The burden on patient morbidity and mortality is immense, and places enormous financial strain on national health systems.[1,2] Antibiotic resistance has emerged as a global public health catastrophe. Antibiotic resistance levels (in individuals and communities) have been shown to wane after reducing antibiotic use,[3,4] and is one of the most important ways to preserve antibiotic benefit.[2,5] The World Health Organisation (WHO) has led the call for all nations to act,[2] and although Australia has made some progress in antibiotic resistance containment efforts, it has lacked the central coordination of more comprehensive international programs that are evident across Europe,[6] the United States of America (USA),[7] Canada,[8] Sweden [9] and Denmark.[10]

Although antibiotic resistance is more apparent in hospitals, and where the focus of containment efforts is most evident, antibiotic use in the community is far greater.[2,3] Acute respiratory infections (ARIs) are one of the most common reasons for primary care consultations and prescribing antibiotics [11] despite evidence they are often ineffective [12-16] and therefore may be unnecessary. Hence, primary care is an important target for developing and implementing effective strategies to safely address the unnecessary use of antibiotics for ARIs. Some of the factors which influence unnecessary antibiotic prescribing in primary care for ARIs appear to be modifiable and are related to clinician-patient communication. These include: some patients request antibiotics as they think they are necessary;[17,18] clinicians perceive that some patients expect an antibiotic (this perception can be inaccurate at times) and feel pressured to prescribe them;[19] and providing a prescription is sometimes an attempt to manage patient satisfaction,[20] conclude a consultation, and maintain the continuity of patient care. Reducing patients' actual and perceived need for an antibiotic has been highlighted as a key global antibiotic resistance strategy.[21] Parents may be a particular focus for primary care intervention, as children more frequently experience an ARI [22] and are prescribed an antibiotic.[23]

There are several promising strategies that could be implemented by primary care clinicians, such as delayed prescribing,[24] near patient testing,[25,26] behavioural 'nudge' techniques,[27] and shared decision making.[28] Of these, shared decision making appears to be well suited to the problem of addressing some of the modifiable factors and communication issues that occur in a consultation. Patients have a tendency to be overly optimistic about treatment benefits and underestimate their harms, and therefore may be less likely to consider the use of an antibiotic if information was presented to them in an accurate and balanced way. Shared decision making, in this situation, is a communication process between the clinician and patient that considers the patient's expectations, beliefs, and preferences about antibiotic use for ARIs, discusses the benefits and harms of both options (using an antibiotic and not using an antibiotic), and invites the patient (or parent) to participate collaboratively in the decision-making process.[29]

However, there are many gaps in the existing shared decision making literature that need addressing as part of considering the appropriateness and effectiveness of this strategy. For example, there is a need to: examine what shared decision making interventions for ARI antibiotic decisions have been developed and whether they are effective; consider the appropriateness of existing interventions for implementation in primary care; and explore parents' beliefs and expectations about antibiotic treatment of ARIs for their children and what level of involvement they desire when treatment decisions are being made.

Objective

The objective of this thesis is to explore the appropriateness of using shared decision making to promote informed choice by parents as a strategy which may reduce or conceivably increase use of antibiotics for ARIs in primary care. To fulfil this objective, three separate studies were conducted, although the findings of Studies 1 and 2, along with other literature, were used to inform the intervention that was developed and evaluated in Study 3. The overall contribution of these individual studies contributes to understanding of the potential for shared decision making as strategy to better manage antibiotic prescribing for ARIs in primary care, as well as generating considerations for its implementation in clinical practice and opportunities for further research.

Research questions

The specific research questions of each of the three studies were:

1. Do interventions that aim to facilitate shared decision making increase or reduce antibiotic prescribing for ARIs in primary care?
2. What are parents' beliefs about antibiotic necessity, their expectations of antibiotic benefit, experiences of other management options, and exposure to and preferences for shared decision making?
3. What is the ability of decision aids to help parents to make an informed choice about antibiotic use for a child with an ARI in a hypothetical scenario, and parents' perceptions of the usefulness and acceptability of the decision aids?

Outline of the thesis

Research questions 1-3 are presented as three independent and interrelated studies, with each representing one chapter in the overall thesis. Each chapter is preceded by a brief preamble to highlight the study within the context of the broader scope of the thesis. An editorial (Chapter 3) emanating from the scoping literature review (Chapter 2), and each of the chapters reporting the studies (Chapter 4, Chapter 5, and Chapter 7), comprise work already published in peer-reviewed journals. For ease of reading and consistency, the published chapters and associated references have been reformatted for consistency within the body of the thesis, and the numbering of figures and tables kept continuous throughout.

Outline of each Chapter

Chapter 2 presents a literature overview of global burden of antibiotic resistance, and identifies international programmes for monitoring antibiotic consumption and/or surveillance of antibiotic resistance in response to the developing public health crisis. It also explains the importance of implementing strategies in primary care, and in particular for ARIs, and identifies strategies that have potential to safely reduce unnecessary antibiotic use for acute respiratory infections in primary care.

Chapter 3 is a published article that focuses on the chronology of Australia's response to WHO's call for the adoption of national strategies to minimise antibiotic resistance. The Chapter identifies a number of resistance surveillance, regulatory, and infection prevention and control measures, predominately focusing on hospital care, and highlights the importance of implementing effective strategies in primary care.

Chapter 4 is a published article which reports a systematic review and meta-analysis to assess whether interventions to facilitate shared decision making reduce antibiotic prescribing for ARIs in primary care, and whether there are unacceptable clinical adverse outcomes or patient dissatisfaction.

Chapters 5 is a published article which presents a nation-wide, cross-sectional survey exploring parents' beliefs about antibiotic necessity for common ARIs in children, quantifies their expectations of antibiotic benefit and awareness of harms, reports the experiences of other management options used for children's ARIs, and parents' exposure to and preferences for shared decision making.

Chapter 6 describes the design and development of brief, evidence-based patient decision aids for ARIs that are commonly seen in Australian primary care (acute otitis media, acute pharyngitis, and acute bronchitis). It discusses them in accordance with the International Patient Decision Aid Standards (IPDAS) quality criteria and provides a rationale for the content and formatting decisions made during the aids' development.

Chapter 7 is a published article which reports the methods and results of the initial stage of a multi-stage evaluation of the decision aids in a randomised trial to assess if they help parents make an informed choice about antibiotic use for a child's ARI in a hypothetical scenario, and to evaluate parents' perceptions about the usefulness and acceptability of the decision aids. It is envisioned that the other stages of evaluation of the aids, such as testing their use in a randomised trial in primary care, will occur following the completion of this PhD research.

While a discussion of individual study findings can be found within each chapter, **Chapter 8** draws these findings together to form conclusions about the appropriateness of shared decision making to reduce antibiotic prescribing for ARIs in Australian primary care, situates the findings within other literature, and presents implications for practice and future research.

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Chapter 2

Literature Review

"Resistance to antibiotics risks health 'catastrophe' to rank with terrorism and climate change."

Dame Sally Davies, Chief Medical Officer, UK.

Preamble to Chapter 2

This Chapter outlines the global health burden of antibiotic resistance, overviews international containment efforts that have been developed in response to the evolving threat, explains the importance of implementing strategies in primary care and in particular ARIs, and identifies strategies that have potential to safely reduce antibiotic use for ARIs in primary care.

The global health threat of antibiotic resistance

Since Alexander Fleming's discovery of penicillin in 1928,[1] and their widespread use after the 1940s when antibiotics revolutionised medicine, bacteria are no longer susceptible to all classes of antibiotics.[2] Bacteria (and other pathogens) are able to develop resistance to antibiotics that have been developed to kill or inhibit their growth.[1] Some bacteria survive by natural selection, growing without competition from susceptible strains.[3] This adaptive process of antibiotic resistance development reduces the effectiveness of antibiotics, and is an inevitable consequence of antibiotic use. This has increased worldwide over recent decades, accelerating the development of antibiotic- (including multi-drug-) resistant pathogens [2] – and is now a global threat to human health.[1] The impending catastrophe is compounded by a worldwide paucity of new antibacterial drug development.[2]

Antibiotic resistance increases the complexity of treatment for a variety of bacterial infections. It can contribute to a delay in effective treatment, or even treatment failure,[1,2] leading to prolonged illness, increased morbidity, higher risk of treatment-or disease-related complications, and higher mortality.[2] Around 50,000 people in the USA [4] and European Union [5] die annually as a direct result of antibiotic (including multi-drug) resistant bacterial infections. Comparable Australian data are presently unavailable, although is likely to be proportional – after adjusting for population differences, this is likely in the order of 1,000-2,000 deaths annually.

In a post-antibiotic era, not only will common infections become incurable once again, but routine medical procedures which require antibiotic cover (such as cancer chemotherapy, organ transplantation, caesarean sections, or complex surgery) will become too risky to embark on.[2] The consequences of this means that, in addition to the substantial health burden, antibiotic resistance will place enormous economic financial burden on nations, with estimates of about USD100 trillion per year in lost productivity.[1,2]

Since available evidence suggest that resistance decays to baseline levels after about one year of stopping antibiotic use, at both the individual and community level, reduction in antibiotic use can conserve their effectiveness.[6,7] Reducing the use of antibiotics is one of the most important strategies that can be employed to contain antibiotic resistance.[2,8]

International antibiotic resistance containment efforts

Broad approaches to contain antibiotic resistance by reducing antibiotic use include surveillance, education, and policy development. The World Health Organisation (WHO) has promoted and facilitated national and regional efforts to do this for more than 15 years.[8] In its seminal 2001 report it called on the United Nations to implement regional surveillance and encouraged support for neighbouring and/or less developed countries.[8] More recently the WHO enlarged on this with five fundamental areas for antibiotic resistance control: surveillance of resistance; regulation of antimicrobial use in humans; regulation of antimicrobial use in animal husbandry; infection prevention and control, and; fostering innovations (research). Political leadership and commitment, alongside coordinated effort, is reinforced as a prerequisite for action in these five domains.[2]

Several well-respected multi-national (such as European Centre for Disease Prevention and Control [9]) and comprehensive national antibiotic resistance surveillance programs (such as DANMAP,[10] Strama,[11] Centres for Disease Control and Prevention,[12] and CIPARS [13]) have emerged during this crucial period. Various monitoring and surveillance systems have been instituted in many other countries and regions. Australian stakeholders have also made substantial progress,[14] notwithstanding the absence of an overarching national framework, in key areas identified by the WHO for containing antibiotic resistance. Evidence from Europe [15,16] and the United States [17] demonstrates decreased antibiotic use is associated with a decrease in levels of resistance.

Primary care: a key target for reducing antibiotic use

Antibiotic use and burden of resistance in the community

The burden imposed by antibiotic resistance on mortality and morbidity is most evident in hospitals, and is therefore where the focus of containment efforts has been. Substantive funding, policy development, and delivery of antibiotic stewardship programs, has enabled centralised administration for the management of antibiotic prescribing in hospital settings.

The situation in the community is different, and infrastructure to support antimicrobial stewardship is not well-established. However, about 80-90% of all antibiotics that are used in human medicine are prescribed in the community.[2,6] The prescription of antibiotics in primary care doubles the odds of detecting antibiotic resistance in a patient's normal body flora two months later.[18] Primary care is where antibiotics are used with least effect, especially for ARIs which account for 15% of all primary care consultations in Australia. These infections are the

single most common indication for prescribing antibiotics,[19] and account for more than half of total ambulatory antibiotic prescribing rates.[19-21] Australian rates of antibiotic prescribing for ARIs in primary care are 4-9 times higher than estimated rates of prescribing recommended by evidence-based clinical guidelines, and most of the antibiotics that are prescribed for ARIs in primary care are unnecessary.[22]

Moreover, many ARIs are also viral in aetiology, and are self-limiting, even if bacterial. Evidence from several systematic reviews conclude antibiotics have little to no benefit for reducing symptom duration or complications in patients with many common ARIs (eg. acute otitis media, sore throat, and acute bronchitis),[23-27] and their use may be outweighed by unnecessary exposure to common (albeit minor) adverse reactions [28] (eg. rash, thrush, abdominal pain, diarrhoea, and vomiting), and of course directly contributing to antibiotic resistance.[7,29] Primary care therefore, seems ripe for the development of interventions that might be effective at reducing unnecessary prescribing. Before listing existing and potential strategies, it is prudent to briefly overview why so many antibiotics are currently being prescribed for ARIs in Australian general practice.

Factors influencing antibiotic prescribing in primary care are modifiable

There are several potentially modifiable clinician- and patient-related factors that influence antibiotic prescribing in primary care. Clinicians may prescribe 'just in case',[30] as it can be clinically difficult (or impossible) to detect a harmless ARI from the early stages of a more serious illness (such as meningococcal meningitis, community acquired pneumonia, peritonsillar abscess, mastoiditis, and even the non-suppurative complications of acute rheumatic fever, or acute glomerulonephritis).[31] They may be prescribed to fill the 'therapeutic vacuum' left when an antibiotic is not indicated and clinicians may sometimes perceive that patients expect an antibiotic and feel pressured to meet this expectation.[32]

Perceived patient demand has been shown to have a significant and independent effect on prescribing,[33] and clinicians are nearly three times more likely to prescribe antibiotics if they believe patients expect an antibiotic.[34] Clinicians may assume their relationship with the patient might be threatened if they do not prescribe an antibiotic,[35] and fear financial loss from losing a patient to another practice.[36] Prescribing an antibiotic for an ARI may also occur in an attempt to reduce consultation length.[35] Antibiotic prescribing for an ARI creates a 'vicious cycle' by encouraging patients to re-consult for similar conditions and reinforcing expectations for an antibiotic prescription.[37]

Clinicians [38] and their patients [39] generally inflate the benefits and underestimate harms of medical treatments, which can lead to unnecessary use of many treatments. Many patients believe that antibiotics are necessary to resolve the clinical symptoms of ARIs,[40] and qualitative studies [41,42] have shown that some parents have misperceptions about the need for antibiotics for ARIs and the consequences of not using them (such as worrying about hearing loss in children who have acute otitis media [42]). Appropriately managing patient expectations about antibiotic benefits and consequences of not using them in consultations for an ARI may be crucial to reducing inappropriate prescribing. Interventions which reduce patients' perceived need for antibiotics and reduce demand was recently identified as one of the global solutions required to manage the antibiotic resistance crisis.[43] Parents of children may be a particular focus for intervention development as children experience more ARIs (between 4 and 12 annually),[44] and are more likely to receive an antibiotic than adults.[45]

Potential interventions to address antibiotic use for ARIs in primary care

There are various interventions that can be used in primary care in an attempt to reduce unnecessary antibiotic use. These have been grouped into broad categories and are briefly described below.

Mass media interventions addressing public perceptions about antibiotic use for ARIs

Public campaigns may have a role in addressing public misconceptions about the effectiveness of antibiotics. There are numerous online and mass media campaigns in high-income countries which aim to promote appropriate antibiotic use. The results of several campaigns suggest that they can decrease the inappropriate use of antibiotics,[46] although the costs are very high, the effects variable, and evidence for a cause–effect relationship lacking. In Australia, NPS MedicineWise has developed a range of consumer education and/or awareness campaigns encouraging consumers to change the behaviours which contribute to antibiotic resistance (e.g. 'Common Colds need Common sense' and 'Become an antibiotic resistance fighter')[47] although the effect on prescribing rates has had little evaluation.

Regulatory measures

Regulatory measures include artificial barriers to prescribing, such as *Authority to Prescribe*, which could be introduced to restrict access to antibiotics for use only with specific

indications.[36] However, such measures are likely to be unpopular with clinicians as this creates an additional time-consuming administrative step.

Non-regulatory interventions which are administered externally

Non-regulatory interventions that are externally administered in primary care include educational materials (such as clinical practice guidelines); educational meetings (such as conferences, lectures, workshops); educational outreach visits that attempt to influence local opinion leaders; audit and feedback; and clinical reminders incorporated into electronic health records.[36] These interventions, when delivered individually, have demonstrated modest reductions in antibiotic prescribing for ARIs in primary care, although multi-component interventions which combine several interventions appear to be more effective.[48-50]

Strategies that can be implemented by individual clinicians in primary care

In Australia, the National Prescribing Service (NPS MedicineWise) has developed online training modules and clinician support tools (symptomatic management and patient counselling tools) which are designed to facilitate clinical decision making in consultation with patients who have ARIs that may not require antibiotics. However, the effectiveness of these is unknown and has not been tested in controlled trials. Patient information leaflets, provided for use during consultations with clinicians, have been shown to reduce antibiotic prescribing,[51] however, the effect size is small, perhaps because passively educating patients has a limited effect on behaviour.[52] A systematic review found that educational interventions which addressed patient–clinician communication were more effective in reducing antibiotics prescribed for childhood ARIs than intervention which targeted either group alone.[53]

Several other interventions that can be implemented by clinicians themselves within their practices have demonstrated potential for safely reducing unnecessary antibiotic use in primary care:

- ***Delayed prescribing*:** When this strategy is used, the clinician prescribes an antibiotic, but simultaneously advises the patient not to have it dispensed until or unless certain criteria about symptoms persisting, or deteriorating, within pre-specified time-frames are met. This strategy enables clinicians, who may not believe that an antibiotic is indicated, to provide a 'safety net' for patients who are perceived to be anxious about not being provided antibiotic. A systematic review of randomised trials found that delayed prescribing reduced antibiotic prescriptions by

62%, without an increase in adverse complications or patients re-consulting again for the same illness, while maintaining patient satisfaction.[54]

- ***Near patient testing***, such as C-Reactive protein (CRP) and procalcitonin, are biomarkers used for identifying patients at risk of serious bacterial infection. Use of these has been trialled with mixed success. A systematic review found that CRP reduced antibiotic prescribing by 19%,[55] and training was brief (<1 hour).[56] A Cochrane review [57] of two trials of using procalcitonin in primary care (involving around 1,000 patients) reported a 40% reduction in antibiotic prescribing. Although near patient testing has been widely embraced in some countries (such as Denmark), its acceptability to Australian clinicians and patients has received little attention, and it has been estimated that is would double the cost of primary care consultations. The costs come from capital outlay for equipment, the running costs of each test, and regular calibration. The costs involved may temper any enthusiasm for widespread use in the current political environment in Australia, particularly while antibiotics remain inexpensive.
- ***Behavioural 'nudge' techniques*** are a simple and low-cost intervention, but have not yet had much evaluation. In one randomised trial, clinicians declared a commitment to antibiotic conservation in a signed poster with a photograph of the doctor that was displayed in the practice. Together with written information that was available to provide to patients, this intervention reduced inappropriate prescribing of antibiotics by 20%.[58]
- ***Shared decision making***, involves a fusion of communication and evidence-based practice skills,[59] in which the clinician explicitly evaluates the concerns, fears, preferences, and expectations of the patient, discusses the benefits and harms of each management option (in this case, the options being antibiotics or none), and invites the patient to participate in the decision-making process.[60] Shared decision making is regarded as the pinnacle of patient-centered care,[61] and in recent years has become widely advocated internationally by policy makers, health professional associations, and consumer groups. Australia currently lags behind many other countries in the implementation and uptake of shared decision making.[62] Sharing in treatment or management decisions may be one of the most important ways of bringing evidence to the point of clinical decisions.[63]

  Interventions to encourage shared decision making, enacted in various ways, has been evaluated by several recent randomised trials of ARIs in primary care.[56,64-72]

These report variable effect estimates and trials have not been synthesised in a systematic review and meta-analysis. However, it appears that it may be a particularly suitable strategy to use to improve the communication and decision making that occurs between clinicians and patients when antibiotics for an ARI are being considered. It would appear especially suited to the problem of antibiotic use for ARIs for several reasons: people have misunderstandings about antibiotic benefits; the likelihood of experiencing benefit or harm from antibiotic use is quite evenly balanced – which makes the decision more sensitive to patient preferences;[60] clinicians' typically report limited exploration and management of patients' expectations;[73] and it focusses on both patients and clinicians.

Shared decision making is the principle focus of the program of research that was conducted for this PhD. However, the extent to and level of involvement that patients prefer in making decisions about antibiotic use for ARIs in Australian primary care is presently unknown. Also unknown is the synthesised effectiveness of shared decision making interventions that have been tested for ARI decision making, and the factors that need to be considered when designing such interventions so that they are effective, acceptable to target users, and easily implementable.

Conclusion

Antibiotic resistance is an inexorable consequence of antibiotic use, and presently one of the greatest threats to public health. Available evidence suggests individual and community level resistance to antibiotics can recede in the absence of antibiotic exposure, and hence strategies to reduce antibiotic use are a priority, particularly in primary care and for ARIs where antibiotics are most used and least necessary. With little available investment and coordination of antibiotic stewardship efforts in primary care, several strategies that can be implemented by clinicians have shown potential to safely reduce antibiotic prescribing. Children who more frequently experience ARIs and receive an antibiotic should be a key target for primary care interventions, as should interventions which target both patients and clinicians. Chapter 3 highlights Australia's response to the evolution of antibiotic resistance.

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Chapter 3

The Antibiotic Crisis: Charting Australia's Path Towards Least Resistance

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Preamble to Chapter 3

The previous chapter (Chapter 2) presented a scoping literature overview of the global public health burden of antibiotic resistance, as well as international and Australian containment efforts in response to the WHO's call for the implementation of national programs to contain antibiotic resistance. The purpose of this narrative was to develop a contextual understanding of the international antibiotic resistance literature.

Chapter 3 [1] consists of an editorial entitled *"*The antibiotic crisis: charting Australia's path towards least resistance*"*, that was published in the *Australian and New Zealand Journal of Public Health* in October 2013. The chapter builds on the previous chapter by chronologically reviewing Australia's response to the global antibiotic resistance crisis over several decades, and identifies important opportunities for primary care research to reduce community use of antibiotics, particularly for ARIs.

Background

Antimicrobial resistance (AMR) is a fast-evolving global public health crisis. The United Kingdom's (UK) Chief Medical Officer calls it a catastrophe ranking with terrorism and climate change [2]. Its consequences are an unenviable return to a pre-antibiotic dawn, rendering many routine infections untreatable [3], and putting much major surgery, organ transplantation and cancer chemotherapy out of safe reach [4]

The World Health Organization (WHO) has called for implementation of programs to contain antimicrobial resistance (AMR) (Box 1). These initiatives are supported by several multi-national [5] and national [6-9] surveillance and stewardship programs. Some have shown decreasing antibiotic use and consequent decreased resistance. Australia has been part of this, although we still have no nationally coordinated surveillance system for antimicrobial use or resistance.

Box 1: Examples of WHO-promoted control programs to be implemented by political leadership: [10]

- surveillance of antimicrobial resistance
- antimicrobial use in humans by regulation
- antimicrobial use in animal husbandry by regulation
- infection prevention and control
- fostering innovations (research)

What has happened in Australia?

Antibiotic resistance appeared on the Australian government agenda in the early 1980s. The evolution of different bodies and responses has been complicated (Table 1). These can be classified into: resistance surveillance; regulatory measures; and infection prevention and control – the latter obviously based on the premise that reducing infection reduces the need for antibiotics. As the table shows, the focus is on hospital care (where the effects of antimicrobial resistance is most keenly felt), although it is actually the community where the greatest tonnage of antibiotics are prescribed (often inappropriately – especially for acute respiratory infections). Health education body NPS MedicineWise is currently focused on this community gap.

Table 1: Some Australian activities in response to antimicrobial resistance

Milestone	Brief elaboration
Resistance Surveillance	
Working Party on Antibiotics (WPA) established by NHMRC (1980s)	To address resistance arising in food animals and spreading to humans [11].
WPA evolved into the Joint Expert Committee on Antibiotic Resistance (JETACAR), reporting in 1999	Proposed antibiotic-resistance management program simultaneously focused on human and animal use of antibiotics – Made 22 recommendations, relating to regulation, monitoring and surveillance, infection prevention strategies, education and research [12].
Commonwealth Response to JETACAR (2000). EAGAR [13] and CIJIG [14] later reported, but momentum was lost	Largely supported recommendations [15] – Proposed establishment of Expert Advisory Group on Antimicrobial Resistance (EAGAR) in 2001 and a Commonwealth inter-departmental JETACAR Implementation Group (CIJIG, 2000).
Strategy for Antimicrobial Resistance Surveillance in Australia (2003)	Strategy to address both JETACAR recommendations for monitoring and surveillance and recommendations relating to surveillance of antibiotic resistance and usage.
Antimicrobial Resistance Summit (2011)	Recommendations to contain antimicrobial resistance and usage, and priorities for a coordinated an interdisciplinary action plan.
Senate inquiry into the implementation of JETACAR (2013) [16]	Recommendations to re-establish an independent national management program for antimicrobial resistance.
National Antimicrobial Utilisation Surveillance Program (NAUSP)	Monitoring antimicrobial usage data in major hospitals.
Australian Group on Antimicrobial Resistance (AGAR)	Prevalence data on important AMR pathogens in Australian hospitals and the community.
National Neisseria Network (NNN)	Resistance trends in Neisseria gonorrhoeae and Neisseria meningitides.
The Sentry antimicrobial surveillance program	Monitors predominant pathogens and resistance patterns for both community-acquired and nosocomial infections globally.
The Surveillance Network (TSN)	Surveillance database of strain-specific AMR test results daily from participating clinical laboratories.

Table 1 (continued): Some Australian activities in response to antimicrobial resistance

Regulatory	
Antimicrobial Resistance Standing Committee (AMRSC) (2012)	Recommendations to contain antimicrobial resistance and usage, and priorities for a coordinated an interdisciplinary action plan. Provide scientific and clinical expertise informing recommendations for national strategies and priorities to minimise antimicrobial resistance. Focus restricted to human health.
The Australian Antimicrobial Resistance Prevention and Containment (AMRPC) Steering Group (2013)	Governance to develop and implement an integrated national antimicrobial resistance containment framework.
National Antimicrobial Resistance (AMR) Prevention and Containment Strategy announced (Budget 2013-14 Portfolio Budget Statement, DoHA)	Recommendations to re-establish an independent national management program for antimicrobial resistance.
Therapeutic Goods Administration (TGA)	'Resistant risk assessments' for new antibiotics (or extensions for indications of existing antibacterials). Revised scheduling of all antibacterials for human use as 'prescription only' (S4).
Pharmaceutical Benefits Scheme (PBS)	Advise EAGAR on the listing and level of access to new antibacterials.
Australian Pesticides and Veterinary Medicines Authority (APVMA)	Prevention of the registration of fluoroquinolones for use in food producing animals [17].
Infection prevention and control	
Healthcare Associated Infection Program, Australian Commission on Safety and Quality in Healthcare	National coordination of several initiatives in public and private health care sectors to reduce HAI.
NPS MedicineWise	National consumer awareness and education campaign. Decision support tools (and Shared Decision Making as a core prescribing competency) for uncomplicated ARIs.

What needs to happen?

First and foremost, a national over-arching body engaged in the process is very important. It looks as if this is happening. In March 2013, a high level steering group was established consisting of the chief health officer; the chief veterinary officer; heads of the Department of Health and Ageing (DoHA) and the Department of Agriculture, Fisheries and Forestry (DAFF); and the CEO of the Australian Commission on Safety and Quality in Health Care. This group supplements the Antimicrobial Resistance Standing Committee [18] established in 2012 to provide technical advice to DoHA on resistance issues.

What can they do? Perhaps they should consider important – if draconian – steps to preserve our antibiotics. Following on the Australian success of the sequestration of quinolones [17], more antibiotics could be put aside for use only with specific patients, with obstructions to access by generalists and junior hospital doctors (such as the Authority to Prescribe), although this approach would be highly unpopular with prescribers. On the surveillance side, we need sentinel general practices (already established in many parts of the world [19] including Australia [20]) to participate in a structured and ongoing surveillance program across the country to gain a better understanding of pathogens and their antibiotic susceptibilities. Compilation and analysis of the vast volume of information from public and private microbiology laboratories would be of immense value.

Other research questions include ways of not just limiting the spread of infection, but the spread of resistance genes themselves (as they have the capacity to jump species and between pathogenic and commensal organisms). We need a better understanding of the contribution of hospitals and the community to resistance, and the extent to which primary care prescribers can reduce their antibiotic prescribing, and whether that will affect resistance generation. To be successful, these initiatives may need to access incentives such as the Practice Incentives Program, or even to address more fundamental factors of our health care system, such as the fee-for-service environment and the right to independent practice. Otherwise we are asking too much of hospital antimicrobial stewardship programs and their nascent community equivalents, such as NPS MedicineWise.

Epilogue to Chapter 3

Since publication of the editorial that is presented in Chapter 3, The Australian Government Departments of Health and Agriculture convened an antimicrobial resistance colloquium, leading to establishment of the Antimicrobial Resistance Prevention and Containment (AMRPC) steering group [21] for providing guidance on developing a National Antimicrobial Resistance Strategy,[22] and ensuring governance and accountability across sectors. The steering group receives expert advice and identifies emerging issues and research priorities from the Australian Strategic and Technical Advisory Group (ASTAG).[22] Within this strategic framework, the Australian Commission on Safety and Quality in Health Care (ACSQHC) established the Antimicrobial Use and Resistance in Australia (AURA) Surveillance System [21] – a nationally coordinated and collaborative antibiotic resistance surveillance and antibiotic consumption monitoring system.

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Chapter 4

Interventions to Facilitate Shared Decision Making to Address Antibiotic Use for Acute Respiratory Infections in Primary Care

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Impact Factor: 6.124
Altmetric score: 138 (August 2017; top 5% of all research outputs and in top 1% of all Cochrane reviews)
34 citations (as of August 2017)

Preamble to Chapter 4

The editorial presented in Chapter 3 documented Australia's chequered response to the evolution of antibiotic resistance over several decades through resistance surveillance, government regulation, and infection prevention and control measures. Finding ways to reduce primary care prescribing of antibiotics, particularly for ARIs where unnecessary use is utmost, was highlighted as a key priority in Chapters 2 and 3. Chapter 2 identified that, compared to hospitals, there has been relatively little investment and coordination of antibiotic stewardship practices in primary care, and several interventions with potential for reducing antibiotic use for ARIs were identified. However, regulatory measures are likely to remain unpopular with clinicians, and various non-regulatory interventions administered externally have individually demonstrated only modest reductions in antibiotic prescribing (and slightly more effective when combined). Several interventions that clinicians are able to implement themselves have also shown promise in safely reducing unnecessary antibiotic use for ARIs. Of these, shared decision making appears particularly suited to the problem, by jointly addressing patients' misperceptions about antibiotic benefits for ARIs, and discussing evidence for the likelihood of experiencing benefit or harm (which are quite evenly balanced and therefore the decision is more sensitive to patient preferences). Several high-quality interventions aiming to facilitate shared decision making in primary care for ARIs have recently emerged, although they have not been synthesised in a systematic review. This is the focus of Study 1 which is presented in Chapter 4.

The research presented in Chapter 4 was accepted for oral presentation at the joint International Society for Evidence Based Health Care and International Shared Decision-Making conference 2015, and the Gold Coast Health and Medical Research Conference 2015, where it was awarded *"Best PhD/Honours Student Podium Award" and "Best of the Best".* Preliminary findings were also accepted for poster presentation at the Primary Health Care Research Conference (PHCRIS), 2014. When accepted for publication by The Cochrane Library, this review was chosen by the Central Cochrane Editorial Unit as a high quality and newsworthy review for which an international press release was issued. This resulted in international media attention and coverage of this research.

Abstract

Background

Shared decision making is an important component of patient-centred care. It is a set of communication and evidence-based practice skills that elicits patients' expectations, clarifies any misperceptions and discusses the best available evidence for benefits and harms of treatment. Acute respiratory infections (ARIs) are one of the most common reasons for consulting in primary care and obtaining prescriptions for antibiotics. However, antibiotics offer few benefits for ARIs, and their excessive use contributes to antibiotic resistance – an evolving public health crisis. Greater explicit consideration of the benefit-harm trade-off within shared decision making may reduce antibiotic prescribing for ARIs in primary care.

Objectives

To assess whether interventions that aim to facilitate shared decision making increase or reduce antibiotic prescribing for ARIs in primary care.

Search methods

We searched CENTRAL (2014, Issue 11), MEDLINE (1946 to November week 3, 2014), EMBASE (2010 to December 2014) and Web of Science (1985 to December 2014). We searched for other published, unpublished or ongoing trials by searching bibliographies of published articles, personal communication with key trial authors and content experts, and by searching trial registries at the National Institutes of Health and the World Health Organization.

Selection criteria

Randomised controlled trials (RCTs) (individual level or cluster-randomised), which evaluated the effectiveness of interventions that promote shared decision making (as the focus or a component of the intervention) about antibiotic prescribing for ARIs in primary care.

Data collection and analysis

Two review authors independently extracted and collected data. Antibiotic prescribing was the primary outcome, and secondary outcomes included clinically important adverse endpoints (e.g. re-consultations, hospital admissions, mortality) and process measures (eg. patient satisfaction). We assessed the risk of bias of all included trials and the quality of evidence. We contacted trial authors to obtain missing information where available.

Main results

We identified 10 published reports of nine original RCTs (one report was a long-term follow-up of the original trial) in over 1100 primary care doctors and around 492,000 patients. The main risk of bias came from participants in most studies knowing whether they had received the intervention or not, and we downgraded the rating of the quality of evidence because of this. We meta-analysed data using a random-effects model on the primary and key secondary outcomes and formally assessed heterogeneity. Remaining outcomes are presented narratively.

There is moderate quality evidence that interventions that aim to facilitate shared decision making reduce antibiotic use for ARIs in primary care (immediately after or within six weeks of the consultation), compared with usual care, from 47% to 29%: risk ratio (RR) 0.61, 95% confidence interval (CI) 0.55 to 0.68. Reduction in antibiotic prescribing occurred without an increase in patient-initiated re-consultations (RR 0.87, 95% CI 0.74 to 1.03, moderate quality evidence) or a decrease in patient satisfaction with the consultation (OR 0.86, 95% CI 0.57 to 1.30, low quality evidence). There were insufficient data to assess the effects of the intervention on sustained reduction in antibiotic prescribing, adverse clinical outcomes (such as hospital admission, incidence of pneumonia and mortality), or measures of patient and caregiver involvement in shared decision making (such as satisfaction with the consultation; regret or conflict with the decision made; or treatment compliance following the decision). No studies assessed antibiotic resistance in colonising or infective organisms.

Authors' conclusions

Interventions that aim to facilitate shared decision making reduce antibiotic prescribing in primary care in the short term. Effects on longer-term rates of prescribing are uncertain and more evidence is needed to determine how any sustained reduction in antibiotic prescribing affects hospital admission, pneumonia and death.

Plain language summary

Review question

We wanted to see if shared decision making was better or worse than usual care in reducing antibiotic prescribing for an acute respiratory infection in primary care.

Background

Shared decision making enables health decisions to be made jointly by a clinician and patient. The decision making occurs after the options and their benefits and harms have been discussed together with the patient's values and preferences. Acute respiratory infections (such as an acute cough, middle ear infection or sore throat) are one of the most common reasons to see a health professional, and antibiotics are commonly prescribed despite good evidence that they have little benefit for these conditions. Any decision to prescribe an antibiotic should be balanced by any benefits against the risk of common harms (such as rash and stomach upset) and the contribution to antibiotic resistance - now a major threat to human health. Shared decision making provides an ideal opportunity within a primary care consultation for greater consideration about the trade-off between benefit and harm of antibiotics for acute respiratory illnesses. Antibiotic prescribing may decrease as a result.

Study characteristics

We identified 10 studies (nine trials and one follow-up study) up to December 2014. In total, the studies involved over 1100 primary care doctors and around 492,000 patients. The intervention was different in each study. Six of the studies involved training clinicians (mostly primary care doctors) in communication skills that are needed to facilitate shared decision making. In three studies, as well as training doctors in these skills, patients were also given written information about antibiotics for acute respiratory infections. All included trials received funding from government sources. No studies declared a conflict of interest.

Key results

Interventions that aim to facilitate shared decision making significantly reduce antibiotic prescribing for acute respiratory infections in primary care, without a decrease in patients' satisfaction with the consultation, or an increase in repeat consultations for the same illness. There was not enough information to decide whether shared decision making affects

other clinically adverse secondary outcomes, measures of clinician and patient involvement in sharing decision making, or antibiotic resistance.

Quality of the evidence

We rated the quality of the evidence as moderate or low for all outcomes.

Table 2: Summary of findings for the main comparison

Shared decision making compared to usual care for acute respiratory infections in primary care						
Patient or population: antibiotic use in acute respiratory infections **Setting:** primary care **Intervention:** interventions to facilitate shared decision making **Comparison:** usual care						
Outcomes	**Anticipated absolute effects[*] (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Risk with usual care	**Risk with Interventions to facilitate shared decision making**				
Antibiotics prescribed or dispensed (6 weeks or less) assessed with: risk ratio	Moderate		RR 0.61 (0.55 to 0.68)	10172 (8 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	47 per 100	29 per 100 (26 to 32)				
Antibiotics prescribed or dispensed (12 months or greater) assessed with: risk ratio	Moderate		RR 0.74 (0.49 to 1.11)	481588 (3 RCTs) [3]	⊕⊕⊖⊖ LOW [1,2]	
	47 per 100	35 per 100 (23 to 52)				
Patient initiated re-consultations for the same illness episode	Moderate		RR 0.87 (0.74 to 1.03)	1861 (4 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	40 per 100	35 per 100 (30 to 41)				
Patient satisfaction with the consultation	Moderate		OR 0.86 (0.57 to 1.30)	1052 (2 RCTs)	⊕⊕⊖⊖ LOW [1,4]	
	71 per 100	68 per 100 (58 to 76)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** Odds ratio; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded one level because of risk of bias: participants in most studies were aware of whether they had received the intervention or not.

[2] Downgraded one level because of imprecision: confidence interval includes reduction and possible increase in use of antibiotics. There was considerable heterogeneity in the rates of antibiotic prescribing during longer-term follow-up (12 months or greater).

[3] Sample numbers in one trial, Butler 2012, were calculated from mean list size at baseline multiplied by the number of participating practices in each group (practice list sizes vary over time and no denominator data were available).

[4] Downgraded one level due to imprecision: confidence interval includes both satisfaction and lack of satisfaction of patients with the consultation.

Background

Description of the condition

Acute respiratory infections (ARIs) are one of the most common reasons for consulting in primary care. Antibiotics are often prescribed,[1-3] often unnecessarily as systematic reviews conclude that antibiotics have little benefit for reducing symptom duration or complications in acute otitis media,[4] sore throat,[5] bronchitis, [6] and sinusitis,[7] and no benefit for laryngitis [2] or colds.[8] The limited benefits of antibiotics for ARIs may be outweighed by unnecessary exposure to common adverse reactions (such as diarrhoea, candidiasis, rash, abdominal pain and/or diarrhoea and nausea and/or vomiting,[9] increased healthcare costs and contribution to antibiotic resistance.[10,11]

Several doctor- and patient-related factors influence clinicians' prescribing behaviour. They include: clinical uncertainty and fear of disease progression; inadequate physician knowledge;[12] underestimates of the contribution of prescribing antibiotics to the development of resistance;[13] and perceived patient expectations for an antibiotic and the subsequent pressure felt to meet this expectation.[14] Antibiotic prescribing for ARIs also creates a 'vicious cycle' through the medicalisation of otherwise uncomplicated and self-limiting illnesses, encouraging patients to re-consult with similar expectations for an antibiotic for similar illness episodes in the future.[15]

Antibiotic use exerts a selection pressure on bacteria to develop resistance.[16] Patients prescribed an antibiotic for respiratory tract infections develop measurable bacterial resistance in their commensal bacteria to that antibiotic for up to 12 months.[11] Although the development of individual resistance is transient, and decays after about a year in the absence of antibiotic use, it is sufficient to sustain high levels of population resistace.[10] Persistent prescribing of antibiotics, and excessive use of broad spectrum antibiotics in place of narrower spectrum ones, are modifiable factors that contribute to resistance.[16] Antibiotic resistance is now an evolving global threat to public health.[16] The rational use of antibiotics is therefore one of the most important strategies for preserving the therapeutic benefit of antibiotic treatment.[16,17]

Description of the intervention

Shared decision making is the process of enabling a health professional and patient to make a joint treatment or management decision based on the best available evidence and the patient's values and preferences.[18,19] It consists of eliciting patients' expectations and clarifying

any misperceptions, discussing treatment options, and communicating the benefits and harms of each option and their likelihood. Shared decision making supports the principle of patient autonomy and the right to self-determination,[20] and has been shown to improve patients' satisfaction with decisions and concordance of decisions with their values.[21] Some of the skills required of clinicians to facilitate shared decision making include proficient communication and rapport building skills as well as access to the best available evidence. It is one of the most important ways of bringing evidence to the point of clinical decisions and a potential strategy for reducing the overuse of ineffective treatments.[20]

How the intervention might work

The diagnostic uncertainty associated with ARIs and the trade-off between the benefits and harms of antibiotics mean that shared decision making may provide an ideal opportunity for clinicians and their patients to choose appropriate treatment or management options, including the decision to not use an antibiotic.[22] By engaging the patient and clinician to explicitly discuss the benefits and harms of antibiotics against a background of evidence demonstrating that it is less effective than most patients expect, there is high potential for it to be effective. Many patients elect for conservative treatment options after participating in shared decision making.[20]

Why it is important to do this review

Concern about antibiotic resistance is now an international public health crisis,[16] and finding ways to minimise unnecessary antibiotic prescribing in primary care is imperative. Shared decision making may be an important process to achieve this. Several related Cochrane systematic reviews have been undertaken. Arnold et al.[23] reviewed the effectiveness of interventions to improve antibiotic stewardship in outpatient care (including the decision to prescribe an antibiotic, and the type, dose and duration of antibiotic therapy). However, broad inclusion criteria and subsequent heterogeneity of the identified interventions limited the generalisability of practice recommendations. Importantly, this review also did not focus on, or explicitly consider, shared decision making interventions for inclusion.

The review by Stacey [24] assessed the effectiveness of decision aids for people facing any treatment or screening decision. Decision aids are only one tool used to facilitate shared decision making in clinical care, and it may be enabled through methods other than, or in addition to, decision aids. Similarly, the review by Kinnersley 2007 [25] evaluated the effect of

interventions to encourage patient health communication and information seeking prior to the primary care consultation that shared some but not all components necessary for shared decision making to occur.[25] Légaré 2010 [26] assessed the effectiveness of interventions to facilitate clinicians' uptake of shared decision making but not the use or effect of shared decision making in a particular condition.[26] The growing interest in shared decision making for potential improvement in treatment decisions and patient outcomes is evident from Cochrane systematic reviews in other clinically important areas including mental health [27] and paediatric oncology.[28] If shared decision making is shown to reduce prescribing among primary care doctors, then steps can be taken to incorporate it into primary care consultations for ARIs across many countries.

Objectives

To assess whether interventions that aim to facilitate shared decision making increase or reduce antibiotic prescribing for ARIs in primary care.

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) (individual level or cluster-RCTs), which evaluated the effectiveness of shared decision making in reducing antibiotic prescribing in primary care. Quasi-RCTs, quasi-experimental studies (controlled clinical trials), controlled before and after studies and interrupted time series analyses were not eligible.

Types of participants

As interventions that aim to facilitate shared decision making may be directed at clinicians, patients, or both, participants eligible for this review could be:

1. clinicians who provide primary care (community practices, hospital-affiliated or government-run outpatient clinics); or
2. patients who present with any combination of symptoms of acute (less than four weeks' duration) respiratory infection (or the parents of similarly affected children).

Types of interventions

There is no one accepted definition of shared decision making;[19] nor is there consensus on the core skills that shared decision making training should address.[29] Therefore, we considered interventions eligible if the trial explicitly stated that the intervention was aimed at facilitating shared decision making or if the intervention explicitly addressed more than one of the essential elements of shared decision making that are described by Makoul 2006.[19] These include: explaining the problem to be addressed; discussing options; communicating benefits and risks of each option; eliciting patient expectations, values, preferences or concerns; discussing patients' ability/self-efficacy; and checking or clarifying understanding.

These elements may have been addressed by providing training in specific skills or providing decision support information or tools (such as decision aids,[24] option grids,[30] or decision boxes [31]), which provide information about relevant issues (such as options, benefits, harms, questions to ask, etc.). The skills training and information/tools could be provided to either clinicians, patients, or both. Interventions may have been delivered in any primary care environment and we imposed no restriction on the training and/or information mode, format or intensity of delivery.

We did not include interventions that consisted solely of the passive provision of patient information without the two-way sharing of information necessary for shared decision making, or which aimed to enhance clinicians' and/or patients' general communication skills.

Types of outcome measures

Primary outcome

1. Prescription of antibiotics (for example, antibiotics prescribed per consultation, or a change in the population rate of antibiotic prescriptions per unit of time).

Secondary outcomes

1. Number or rate of patient-initiated re-consultations for unresolved ARI (i.e. same illness episode).
2. Incidence of colonisation with, or infection due to, antibiotic-resistant organisms.
3. Incidence of hospital admission.
4. Incidence of pneumonia (clinical with radiological confirmation).
5. Incidence of acute otitis media complications (for example, tympanic membrane perforation, contralateral otitis (in unilateral cases), mastoiditis, meningitis).

6. Mortality due to respiratory illness or similar.
7. All-cause mortality.
8. Measures of patient and caregiver satisfaction.
9. Measures of patient and caregiver satisfaction with the decision reached, decisional conflict and decisional regret.
10. Measures of extent of patient involvement in the decision making process (for example, consultations analysed using tools such as the OPTION instrument.[32]).
11. Measures of treatment compliance or adherence to decision reached.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL 2014, Issue 11), which includes the Cochrane Acute Respiratory Infections Group's Specialised Register, MEDLINE (1946 to November week 3, 2014), EMBASE (2010 to December 2014) and Web of Science (1985 to December 2014).

We searched MEDLINE using the search terms described in Supplementary material: Table S15. We combined the MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision); Ovid format. We used the MEDLINE search strategy to search CENTRAL and adapted it to search EMBASE and Web of Science. Supplementary material: Table S15. We imposed no language, publication date or publication status restrictions on the electronic database searches.

We searched the National Institutes of Health registry of clinical trials (www.clinicaltrials.gov) and the World Health Organization's (WHO) clinical trials registry (www.who.int/ictrp/en/) for completed and ongoing studies eligible for inclusion. We searched Web of Science and EMBASE to identify potentially relevant conference abstracts and proceedings.

Searching other resources

We searched the bibliographies of retrieved articles and published reviews for additional studies. We personally communicated with trial authors of significant publications and content

experts (Professor Paul Little, Professor Christopher Butler and Professor France Légaré) to identify further published, unpublished or ongoing trials.

Data collection and analysis

Selection of studies

We merged search results into reference management software (Endnote X6) and removed duplicate references. Two review authors (PC, LM) independently screened the titles and abstracts of retrieved records. We attempted to identify multiple reports of single studies following the criteria recommended in the Cochrane Handbook for Systematic Reviews of Interventions.[33] We retrieved full-text copies of all potentially relevant articles for full-text evaluation. The final list of eligible trials was confirmed following discussion and consensus among review authors (PC, TH, LM, CDM).

Data extraction and management

Two review authors (PC, LM) independently extracted data from each included trial using a specifically designed electronic data extraction form. We resolved disagreements by discussion and consensus, with one review author (CDM) acting as arbitrator where required.

Data extraction was blind to names of authors, institutions and publication title. We extracted the following key study features where available:

1. Trial characteristics and methodological quality – risk of bias (see below); trial design, including unit of randomisation and number of comparator arms; blinding; generation of allocation sequence; allocation concealment; number of participants; theoretical or conceptual basis of the intervention; number of intervention components; description of intervention and comparator arms; length of follow-up; sample size estimate (power calculation); number of patients randomised to each intervention arm; number of patients completing the trial; reasons for withdrawal; and intention-to-treat (ITT) or per protocol analysis.
2. Patient (and/or caregiver) characteristics - age, gender and sociodemographic variables; types of ARI; duration of ARI prior to study recruitment; co-morbidities.
3. Healthcare professional characteristics – age; gender; experience; primary care setting type.

4. Outcome measures – all primary and secondary outcomes.

Assessment of risk of bias in included studies

Two authors (PC, LM) independently assessed the risk of bias of included studies and two acted as arbitrators (TH, CDM). We assessed risk of bias using the 'Risk of bias' tool available in RevMan 2014 and the criteria explained in the Cochrane Handbook for Systematic Reviews of Interventions.[33] We assessed the reliability of the sequence generation, allocation concealment, blinding (participants, personnel and outcome assessors), incomplete outcome data and selective outcome reporting bias, as well as other sources of bias. We ranked studies as high, low or unclear risk of bias as described in the Cochrane Handbook for Systematic Reviews of Interventions and present our assessments in a 'Risk of bias' summary figure.[33] As all included studies were cluster-RCTs, we assessed additional sources of bias including recruitment bias, baseline imbalance between clusters, loss of clusters and incorrect analysis.[33]

Measures of treatment effect

Measures of treatment effect included dichotomous (binary), rate and continuous primary or secondary outcome data. Some studies calculated mean difference (MD) for continuous outcomes (median difference or median and interquartile range where data are not normally distributed) and for dichotomous outcomes, risk ratio (RR), odds ratio (OR) or rate ratio (RaR) were reported. In accordance with our protocol we have based the primary analysis on data reported as adjusted risk ratios. Additional analyses of the prescribing outcomes also present adjusted odds ratios and risk differences to incorporate additional information as analysed in the included studies.

Unit of analysis issues

Studies presented effect measures adjusted for clustering effects (at practice, provider and/or patient hierarchies) or potential confounders in multilevel analysis, and/or applied generalised linear mixed models or generalised estimating equations. Intraclass correlation coefficients were estimated in sample size calculations,[34-39] or reported,[34,36] to account for clustering effects. Where intraclass correlation coefficients were not reported,[40,41] we imputed them from another similar included study.

Dealing with missing data

The majority of studies performed ITT analyses.[34-36,38-40,42] One study presented data only from practices with complete follow-up.[12] The long-term follow-up study of Cals 2009 [35] included data only where medical records could be accessed for the follow-up period (87.9% of original trial cohort).[41] The principle of analysis was not stated in one study.[37] Drop-out rates and contributing reasons were sufficiently disclosed in all studies, and one study reporting relatively high attrition performed a sensitivity analysis to explore effects from differential missing values.[12]

Assessment of heterogeneity

We used a random-effects model for all meta-analyses due the observed methodological diversity and used the I^2 statistic to measure heterogeneity as recommended in the Cochrane Handbook for Systematic Reviews of Interventions.[33]

Assessment of reporting biases

We minimised reporting bias by conducting a comprehensive search for studies that met the eligibility criteria, including grey literature and unpublished trials; and by contacting trials authors for missing information. There were insufficient studies to test for publication bias using a funnel plot.

Data synthesis

Meta-analyses of studies were limited to studies reporting a comparable effect estimate. Therefore, the test for overall effect is limited to analysis in each subgroup. Studies reporting data that could not be combined for meta-analysis are reported narratively. Forest plots were also not generated for data reported by a single study, or where the synthesis of available pilot data to the substantive study (for example, Légaré 2011 [42]) would not meaningfully increase the power or precision of observed effects. Similarly, meta-analyses of secondary outcomes were limited to studies reporting comparable measures, those providing similar effect estimates or where there were sufficient trials for comparison (such as patient satisfaction with the consultation). Caution is warranted for conclusions for each outcome due to the low numbers of trials for each comparison. We used RevMan 2014 to enter and analyse data to estimate a weighted treatment effect (with 95% confidence intervals (CIs)). We analysed data using the

random-effects model due to the expected heterogeneity in combining diverse shared decision making interventions.

We created Summary of findings (Table 2) using the following outcomes: antibiotic prescribing in the short term (less than six weeks), longer-term antibiotic prescribing (12 months or longer), re-consultation for the same illness episode and patient satisfaction with the consultation. We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of evidence of the studies contributing data for meta-analyses of prespecified outcomes.[43] We used the methods and recommendations described in Section 8.5 and Chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions,[33] using GRADEpro GDT software.[44] We justified decisions to downgrade or upgrade the quality of studies using footnotes and comments to aid the reader's understanding of the review.

Subgroup analysis and investigation of heterogeneity

There were insufficient studies to conduct a subgroup analysis of trials that incorporate shared decision making as part of a multifaceted intervention compared with trials in which shared decision making was the standalone intervention. Subgroup analysis of interventions

targeted at clinicians versus patients/parents was also not conducted due to a lack of studies. We did not conduct planned subgroup analyses of children versus adult trial populations, trials with low risk of bias versus high risk, and cluster-RCTs versus individually randomised studies due to insufficient studies.

Sensitivity analysis

Insufficient studies prevented a planned sensitivity analysis excluding trials found to have a higher versus low risk of bias to examine the effect of trial quality on the magnitude and direction of effect.

Results

Description of studies

Results of the search

We retrieved a total of 3272 studies from the searches of the electronic databases after duplicates were removed. Two review authors (PC, LM) independently screened record titles and abstracts and, following consensus, 3256 records did not meet our inclusion criteria and were excluded. A recent published study protocol was identified and we contacted the lead author to confirm the study was ongoing and study results would not be available in time for this review [45] We retrieved full-text reports of the remaining 16 records and two review authors (PC, LM) screened these independently. We excluded six studies after they did not meet the a priori eligibility criteria for shared decision making interventions. All review authors (PC, TH, LM, CDM) considered the provisional list of 10 studies for inclusion. We contacted trial authors of two of these studies for further elaboration on respective study interventions to determine that both were eligible for inclusion.[12,34] We included 10 published reports of nine original studies: one publication reports long-term follow-up outcome data of an earlier study,[41] and another published report, Légaré 2011,[42] presents pilot data for relevant outcomes distinct from the subsequent substantive cluster-RCT. [37]. See Figure 1

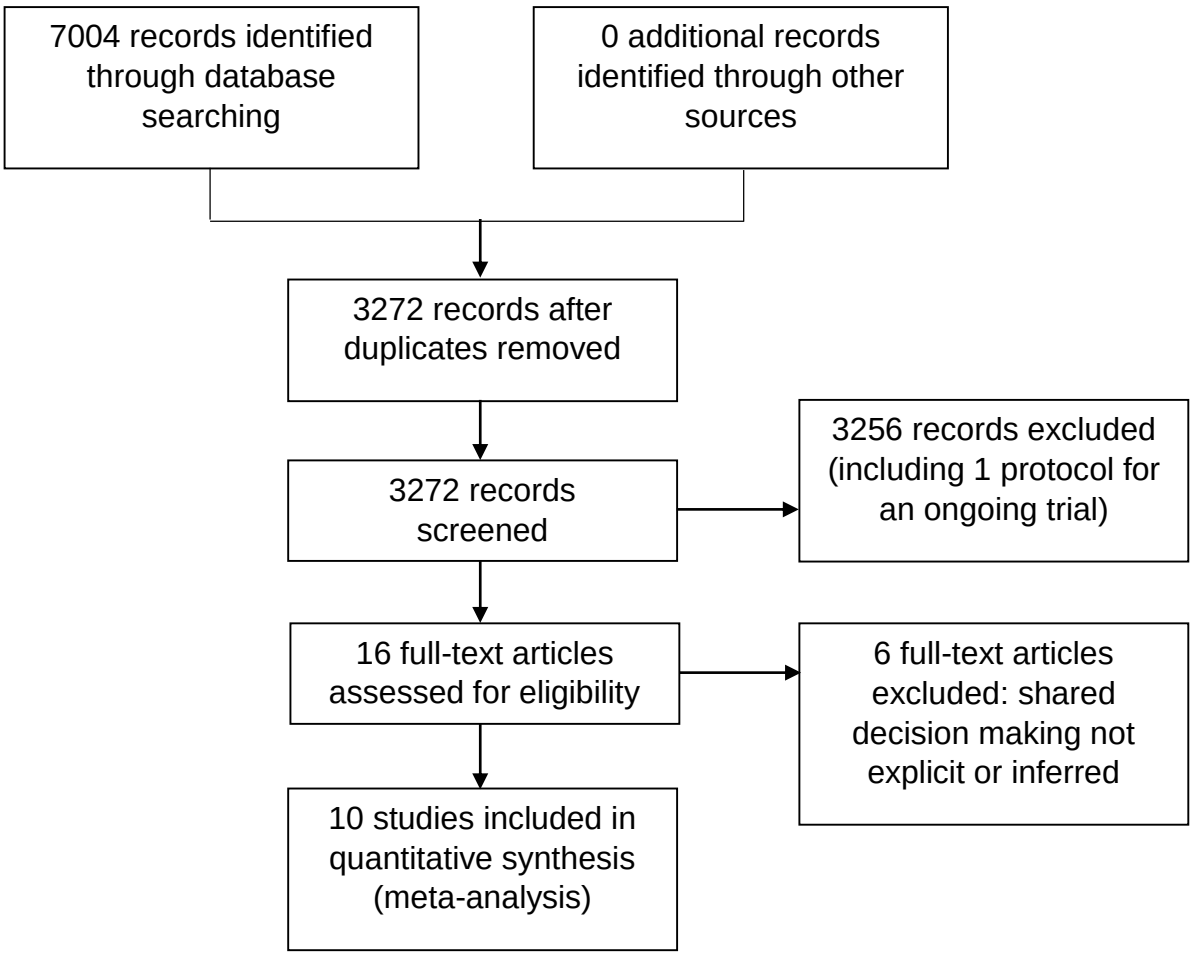


Figure 1: PRISMA study flow diagram

Included studies

Study design

Six studies used a two-arm randomised group design: experimental versus control (usual care).[12,36,37,39,40,42] In one study the control group received the intervention after the experimental group had been exposed to the programme.[42] Briel 2006 [34] compared three arms: full intervention versus limited intervention versus non-randomised controls that acted as distractors to the intention of the real comparison and were not analysed. Two studies compared four parallel study arms: intervention (a) versus intervention (b) versus intervention (a + b) versus control.[35,38] These two cluster-RCTs incorporated a pre-specified factorial

analysis plan.[35,38] Trial data for interventions not relevant to the present review (such as C-reactive protein point of care testing [35,38] or costs [40]), are not presented. All nine original studies included were cluster-RCTs. The unit of randomisation in studies was the general practitioner (GP),[12,34] general practice,[35,36,38,40] GP peer review group,[39] family practice teaching unit,[37] and family medicine group.[42]

All trials received funding. None disclosed conflicts of interest except Cals 2013 [41] (one study author received travel/lecture funds from a point of care test device manufacturer being evaluated in the study, for which data were not relevant to this review). Ethical approval was documented in all studies.

Characteristics of settings and participants

The studies were conducted in Germany,[12] Switzerland,[34] the Netherlands,[35,39,41] Englan,[36] Wales,[36,40] and Canada.[37,42] One multinational trial was conducted across six European countries (Netherlands, Belgium, Spain, Poland, England and Wales).[38]

Recruitment of clinicians

Participating general practitioners (GPs) were recruited directly,[12,34] or through participating general practices,[35,36,38,40] peer review groups,[39] family practice teaching units,[37] or family medicine groups.[42]. The existing nationwide structure of GP peer review groups in the Netherlands comprise GPs and collaborating pharmacists that aim to promote rational prescribing through audit and feedback.[39] UK general practices comprise GPs and nurse prescribers.[38] GPs within Family Medicine Groups in Canada (Quebec) also work closely with nurses for care of registered individuals.[42] Family Practice Teaching Units in Quebec include both physician teachers and residents.[37]

Recruitment of patients

Specific ARI diagnoses and participant eligibility varied a little across studies. In several studies GPs recruited all patients (adults and children accompanied by a legal guardian),[37,39,42] or only adult patients,[34] consulting with symptoms of ARI. One study included adult patients presenting predominately with acute lower respiratory tract infections (LRTIs) and upper respiratory tract infections (URTIs).[38] Cals 2009 [35] included adult patients only with suspected LRTI. Altiner 2007 [12] restricted patient eligibility to patients over 16 years of age consulting for acute cough. Conversely, Butler 2012 [40] included patients with any condition registered with

participating practices. Francis 2009 [36] included only children (six months to 14 years) and their parents consulting for a respiratory tract infection. Study exclusion criteria also differed a little among studies. Asthma was an explicit exclusion criterion in two studies,[12,36] and was not reason for exclusion in another.[39] Patients with chronic obstructive pulmonary disease (COPD) were ineligible in one study,[12] although were eligible for inclusion in two trials.[34,39] The proportion of patients diagnosed with asthma/COPD ranged from ~ 2% to ~ 3.5% [7,42] up to ~ 18.5%.[38] Patients with pneumonia were excluded from participation in one study.[34] However, they were eligible in two studies,[38,39] and this was diagnosed in ~ 3.5% of participants in Welschen 2004.[39]

Characteristics of interventions and comparisons

Interventions

Included trials assessed various multi-component interventions primarily aimed at facilitating clinicians shared management of decisions to reduce antibiotics for ARIs and their related symptoms in primary care.

The delivery of interventions occurred in usual clinical settings or central locations, and varied in intervention elements and scope and the frequency and duration (i.e. intensity) of sessions. All studies provided education and communication skills training that aimed to improve GPs' understanding of topics such as: the probability of bacterial or viral ARI; evidence for the benefit/risk of antibiotics and/or other treatment options; risk communication techniques; information exchange about symptoms and natural disease course; methods of eliciting patients' concerns and expectations; and agreement with the patient about a management plan and summing up. Communicative techniques used were derived from various theoretical models or frameworks.

Training in specific education and communication skills was delivered through peer- or facilitator-led interactive workshops and seminars or via web-based platforms, and supported with the use of videos, interactive exercises and decision aids or interactive booklets to facilitate patient participation in treatment decisions. Other programme components in some studies included consensus procedures, simulated patient consultations, personal reflection on clinical practice, reminders of expected behaviours and provision of antibiotic resistance trend data. Several interventions contained materials developed for patients, including education materials in waiting rooms (poster and leaflet), an interactive booklet for use within the consultation and as a take home resource, or decision support tool).

A summary of the main intervention components is described using the items from the Template for Intervention Description and Replication (TIDieR) checklist.[46] (Supplementary material: Table S4).

Comparators

In all trials the comparator was usual care, with the exception of Briel 2006 [34] where GPs received training in a two-hour seminar on evidence-based US guidelines for ARIs.

Excluded studies

We excluded six studies as shared decision making was not explicit or inferred in the interventions evaluated (Characteristics of excluded studies).

Risk of bias in included studies

The methodological characteristics of the studies are reported in the Characteristics of included studies table. The 'Risk of bias' summary and 'Risk of bias' graph are presented in Figure 2 and Figure 3, respectively.

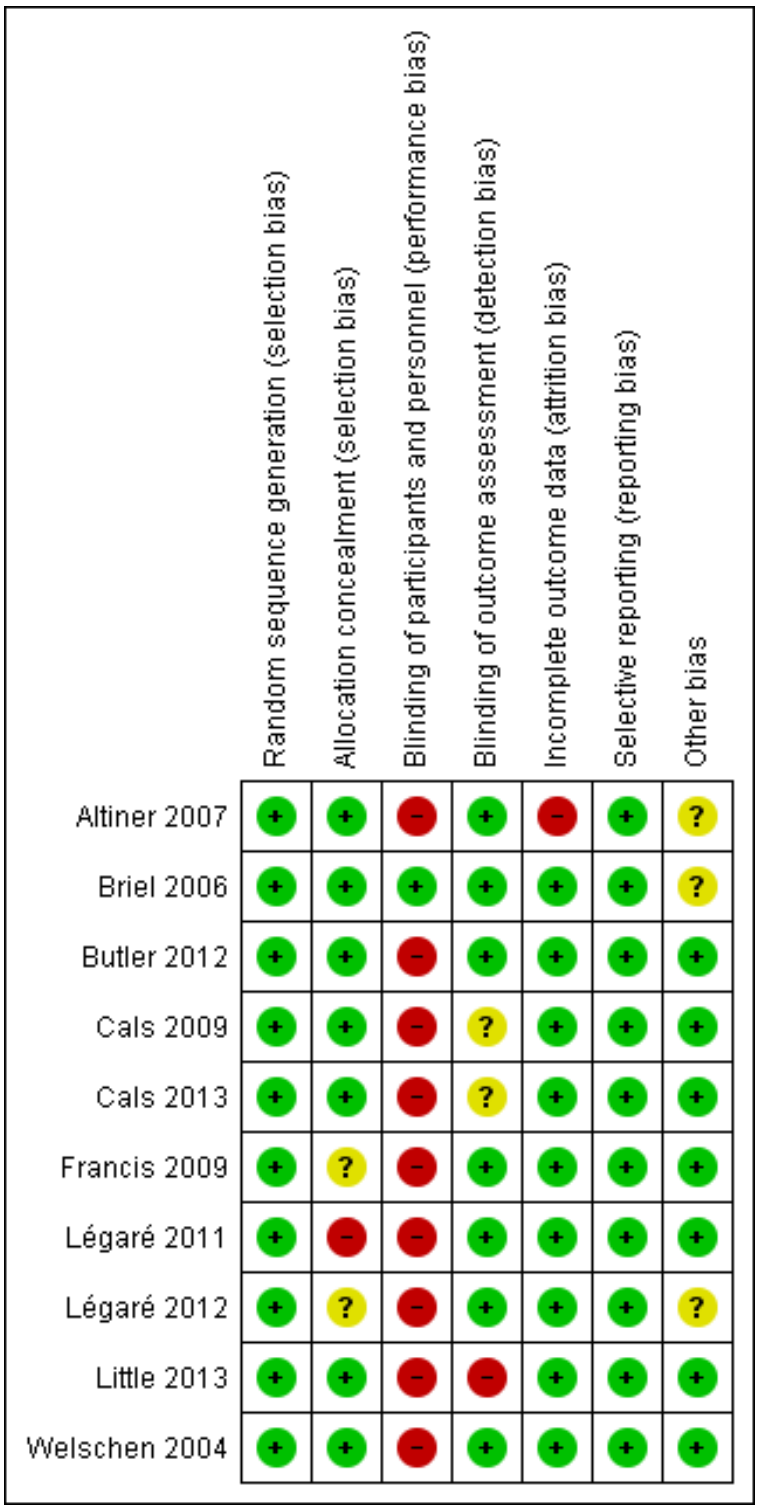


Figure 2: 'Risk of bias' summary: review authors' judgement about each risk of bias item for each included study

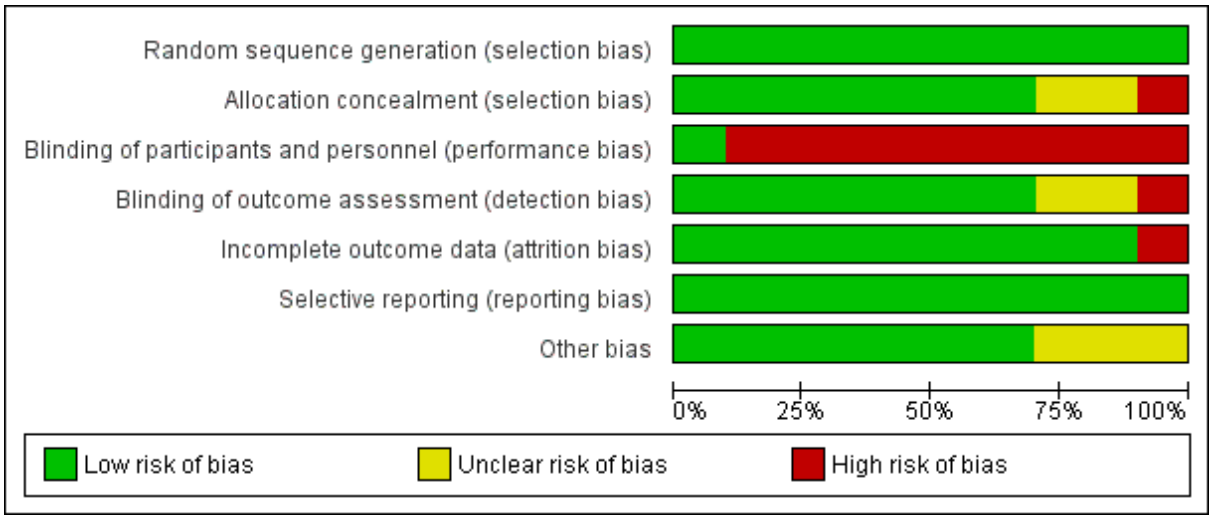


Figure 3: 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Allocation

Methods of sequence generation comprised computer and/or program-generated methods.[12,34,36-38,42] Studies used stratification and minimisation techniques,[38] or dynamic block allocation,[36,40] to achieve balanced groups on selected variables.

Concealed allocation occurred in most trials, with GPs blinded to group allocation until after randomisation, although methods of doing so were not clearly described in several trials.[12,34-36,38,39] In Légaré 2012,[37] the family practice units were recruited before randomisation, but it is not clear when physicians in the units were recruited/consented. In Légaré 2011,[42] individual family physicians were recruited after randomisation of the family medicine groups.

Blinding

The nature of the interventions meant blinding of the clinicians delivering the intervention was not possible. Briel 2006 [34] reported blinding of general practitioners although this is not credible. Blinding of outcome assessment was not reported in Little 2013,[38] although it was adequately described in all other included studies.

Incomplete outcome data

One study had high risk of attrition bias. Altiner 2007 [12] reported that 17% of GPs were lost to follow-up at six weeks post-intervention and 41% at 12 months. The study authors explored the effect of high attrition by conducting a cluster level sensitivity analysis by imputing new values for missing average antibiotic rates: firstly, by performing a regression analysis according to GPs with complete data sets to receive a prediction rule of six weeks and 12 months prescribing rates from baseline prescribing rates and, secondly, by using these rules to estimate follow-up prescription rates for those physicians that dropped out of the study. Alternative estimates using last observations (baseline or six weeks) were similar, and the results of both sensitivity analyses were in line with reported results. Légaré 2012 [37] reported that three of 12 randomised family practice teaching units were lost to follow-up. The loss of clusters was noted as a study limitation, but no further analysis was performed. Neither of these studies reported conducting statistical analysis on an intention-to-treat (ITT) basis. The risk of attrition bias was low in the remaining studies.

Selective reporting

Several studies reported prospective trial registration,[35-38,40,41] and/or had published trial protocols.[35-37,40,42] We detected no reporting bias by comparing these to the final reports. Only Briel 2006 [34] neither reported trial registration nor published a protocol.

Other potential sources of bias

We considered recruitment bias to be minimal in the included trials as the unit of allocation was recruited into the trial before clusters were randomised. Similarly, we considered baseline imbalances between study group characteristics minimal as all studies disclosed baseline comparability and adjusted for important baseline differences in the analysis. In two studies there was sufficient loss of clusters following randomisation that may have introduced bias.[12,37] All studies sufficiently reported the use of robust statistical methods to account for clustering in the analysis.

All studies reported a sample size calculation with the exception of Légaré 2011,[42] which was designed as a pilot trial. An ITT analysis was pre-specified in all but two trials.[12,37] Altiner 2007 [12] included only practices with complete follow-up in the analysis and the method of analysis was not described in Légaré 2012.[37]

The methods, timing and duration of patient recruitment varied across studies. Recruitment in some trials was planned to capture winter and/or autumn months.[35-37,39] In the long-term follow-up study, Cals 2013,[41] of the original cluster-RCT,[35] the end date of the follow-up period was chosen to ensure a similar number of winter days in each period. Recruitment in the Little 2013 [38] study occurred at the end of the season for respiratory tract infections in participating European countries (February and May). One trial included registered practice populations over an entire year.[40] The timing and duration of participant recruitment (e.g. during limited/winter months versus annual periods) may influence study outcomes and seasonal variation in the frequency and severity of ARIs may affect results.

The possibility of selection bias remains a possibility, although trial authors report that the risk of bias was minimal as baseline GP and patient characteristics were disclosed in all studies and no systematic differences between known group characteristics or case-mix were observed. Altiner 2007 [12] could not rule out that GPs, who were not monitored during the trial, may not have reported patients with acute cough who received an antibiotic. Participating GPs in Briel 2006 [34] were considered highly motivated and several authors considered the possibility that GPs may have behaved differently while being monitored (Hawthorn effect).[34,36]

Intervention adherence was measured in only a few trials. Treatment fidelity was not measured in any of the included studies and sub-optimal exposure or delivery of the intervention as planned may dilute the observed effect.

Effects of interventions

Primary outcome

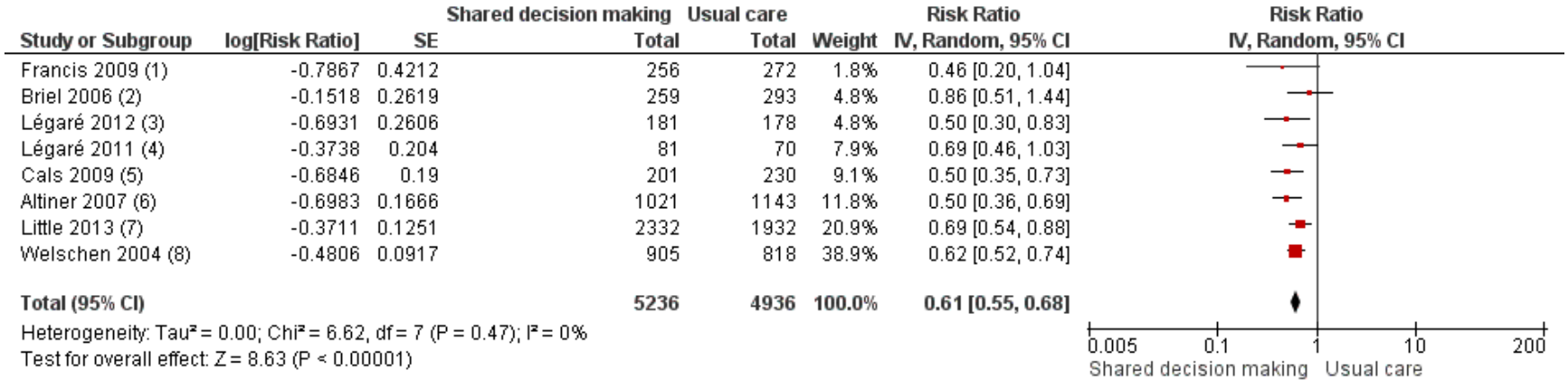
Prescription of antibiotics

There were data from all 10 included studies on antibiotic prescribing decisions for acute respiratory infection. However, they could not all be combined into one meta-analysis because of differences in adjusted effect estimates reported and outcome measurement time.

We extracted event and denominator data, and reported (or imputed) intra-class correlation coefficients, to calculate the risk ratio (RR) adjusted for the effects of clustering (Analysis 1.1; Analysis 1.2) to allow presentation of outcome data within a common scale. This also allowed us to combine trials reporting short (index consultation to ≤ six weeks) and longer-term (≥ 12 months) intervention effects on antibiotic prescribing. Eight studies reporting short-term prescribing outcomes could be pooled in meta-analysis: the RR compared to usual care

was 0.61, 95% confidence interval (CI) 0.55 to 0.68; P value = < 0.001 (Figure 4). There was a trend towards a reduction in antibiotic prescribing being maintained in the longer term: RR compared with usual care 0.74, 95% CI 0.49 to 1.11; P value = 0.14 (Figure 5). However, the non-significant results may be an artefact of the more conservative effect estimates using RR adjusted only for clustering.

We also conducted a sensitivity analysis by pooling the results of trials reporting similar adjusted effect estimates (see Analysis 1.3; Analysis 1.4; Analysis 1.5). Three studies reported antibiotic prescription as an odds ratio (OR) adjusted for clustering and other covariates, and we were able to meta-analyse them: the pooled OR compared with usual care was 0.44, 95% CI 0.26 to 0.75; P value = 0.003 (Figure 5). Similarly, a meta-analysis of two studies reporting a RR adjusted for clustering yielded a pooled RR compared with usual care of 0.64, 95% CI 0.49 to 0.84; P value = 0.001 (Figure 6). A meta-analysis of four studies reporting an adjusted risk difference (RD) yielded a pooled RD of -18.44%, 95% CI -27.24 to -9.65% compared with usual care (Figure 7). The results of the primary meta-analysis (RR adjusted for clustering) are generally concordant with trials reporting comparable adjusted effect estimates, although not adjusting for covariates that may have differed slightly between randomised groups (which were adjusted for in the reports) results in some loss of precision and wider 95% CIs.



Footnotes

(1) Reported intra-class correlation co-efficient (ICC) = 0.24. Design effect and effective sample size calculated.

(2) Reported intra-class correlation co-efficient (ICC) = 0.04. Design effect and effective sample size calculated. Actual sample denomiator used to calculate risk ratio....

(3) Adjusted for cluster design, baseline values and patient age group (for analyses at teaching unit and physician levels).

(4) Reported intra-class correlation co-efficient (ICC) = 0.02. Design effect and effective sample size calculated.

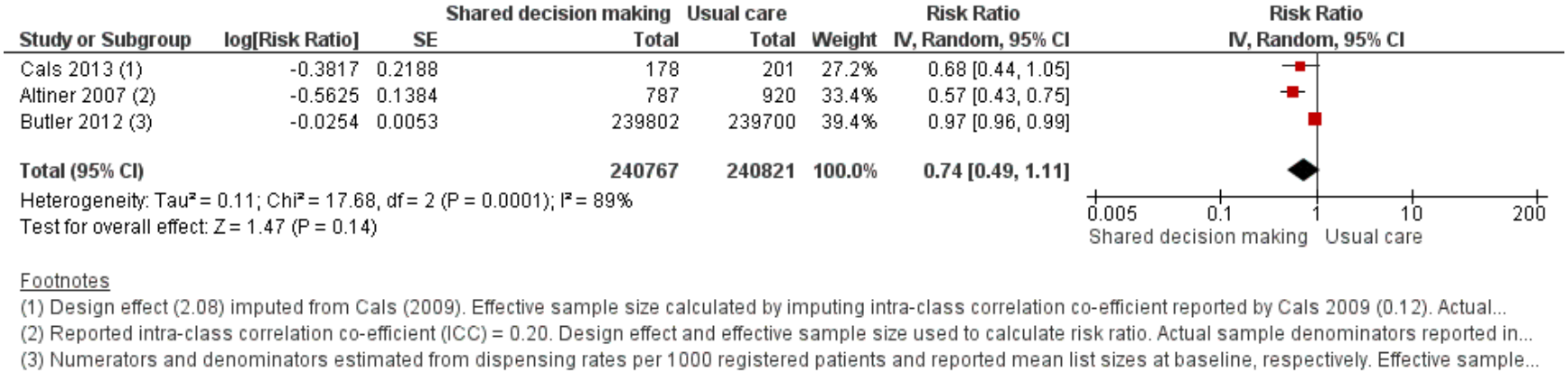
(5) Reported intra-class correlation co-efficient (ICC) = 0.12. Design effect and effective sample size used to calculate risk ratio. Actual sample denominators reported in...

(6) Reported intra-class correlation co-efficient (ICC) = 0.20. Design effect and effective sample size used to calculate risk ratio. Actual sample denominators reported in...

(7) Adjusted for baseline prescribing and clustering by physician and practice, age, smoking, sex, major cardiovascular or respiratory comorbidity, baseline symptoms,...

(8) Reported intra-class correlation co-efficient (ICC) = 0.09. Design effect and effective sample size used to calculate risk ratio. Actual sample denominators reported in...

Figure 4: Forest plot comparison: 1 Shared decision making versus usual care (control), outcome: 1.1 Antibiotics prescribed, dispensed or decision to use (short-term, index consultation to ≤ 6 weeks)



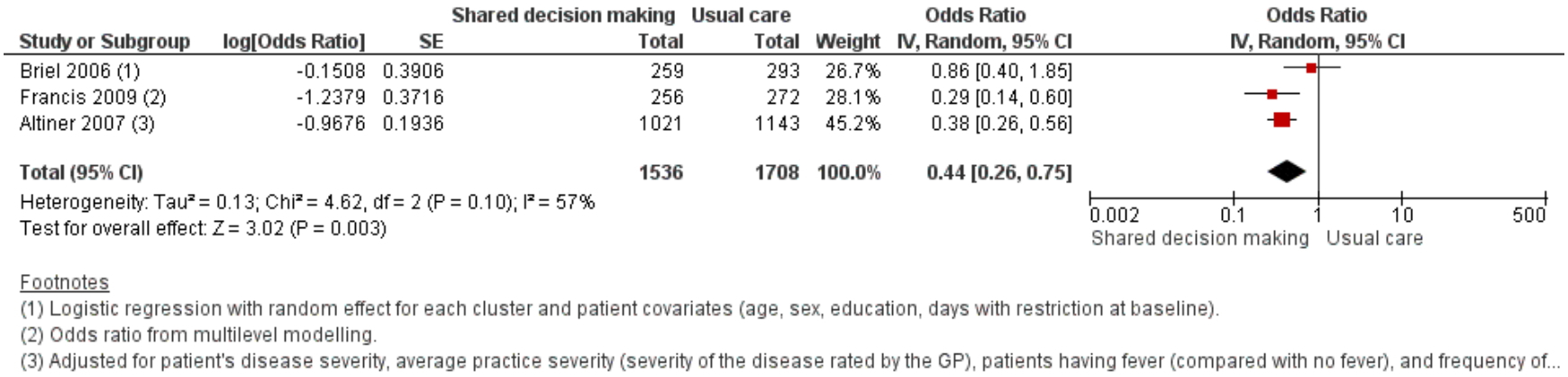
Footnotes

(1) Design effect (2.08) imputed from Cals (2009). Effective sample size calculated by imputing intra-class correlation co-efficient reported by Cals 2009 (0.12). Actual...

(2) Reported intra-class correlation co-efficient (ICC) = 0.20. Design effect and effective sample size used to calculate risk ratio. Actual sample denominators reported in...

(3) Numerators and denominators estimated from dispensing rates per 1000 registered patients and reported mean list sizes at baseline, respectively. Effective sample...

Figure 5: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.2 Antibiotics prescribed or dispensed (longer-term, ≥ 12 months)



Footnotes

(1) Logistic regression with random effect for each cluster and patient covariates (age, sex, education, days with restriction at baseline).

(2) Odds ratio from multilevel modelling.

(3) Adjusted for patient's disease severity, average practice severity (severity of the disease rated by the GP), patients having fever (compared with no fever), and frequency of...

Figure 6: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.3 Antibiotic prescriptions (index consultation) (adjusted odds ratio)

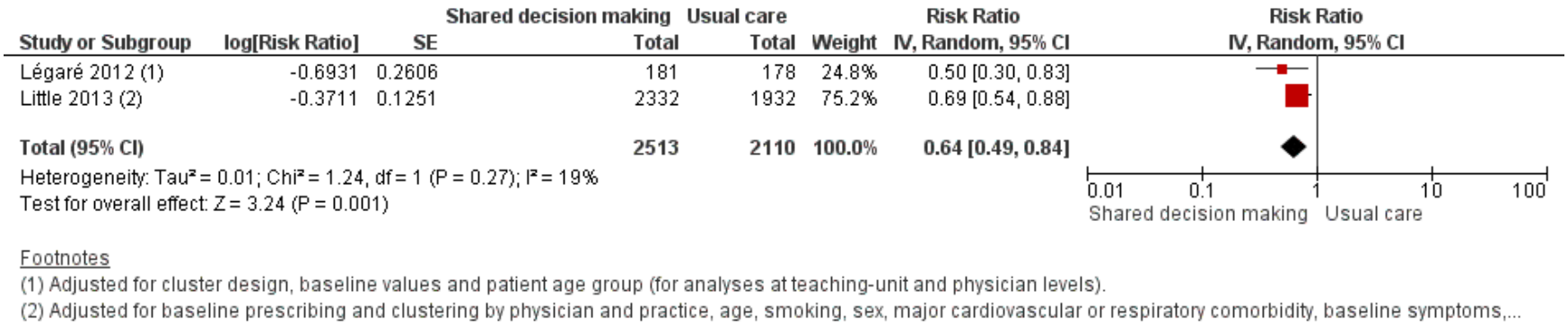
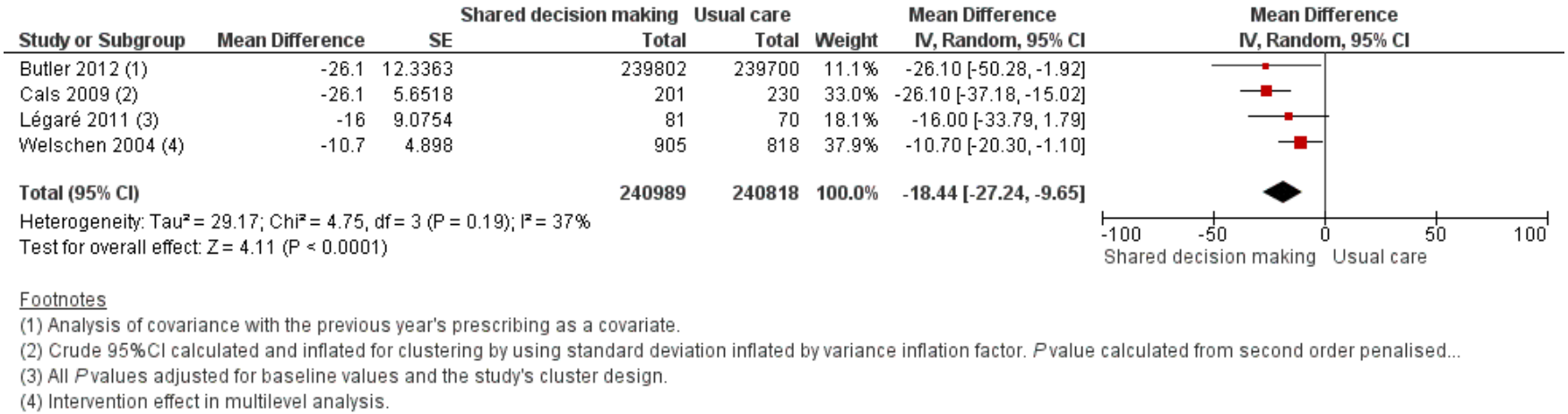


Figure 7: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.4 Antibiotic prescriptions (index consultation) (adjusted risk ratio)



Footnotes

(1) Analysis of covariance with the previous year's prescribing as a covariate.

(2) Crude 95%CI calculated and inflated for clustering by using standard deviation inflated by variance inflation factor. *P* value calculated from second order penalised...

(3) All *P* values adjusted for baseline values and the study's cluster design.

(4) Intervention effect in multilevel analysis.

Figure 8: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.5 Antibiotic prescriptions (index consultation or population rate per unit of time) (adjusted risk difference)

The absolute effect of the intervention for the outcome of antibiotics prescribed, dispensed, or decision to use, immediately after, or within six weeks, of the consultation was reduced from 47% to 29%.

Francis 2009 [36] showed important reductions in antibiotics prescribed for children consulting for an ARI at the index consultation (intervention versus control: 19.5% versus 40.8%; adjusted OR 0.29; 95% CI 0.14 to 0.60). Francis 2009 [20] was the only trial that also reported data on antibiotics taken (this was collected by telephone questionnaire). They reported the percentage of participants in each group that took antibiotics within the first two weeks (the data also include the antibiotics that were prescribed after the index consultation: 50 (19.5%) in the intervention group and 111 (40.8%) in the control group, with an adjusted OR of 0.35, 95% CI 0.18 to 0.66). A significant decrease in antibiotic prescriptions for acute cough was observed in Altiner 2007 [12] at six weeks (adjusted OR 0.38, 95% CI 0.26 to 0.5; P value < 0.001) and 12 months (adjusted OR 0.55, 95% CI 0.38 to 0.80; P value = 0.002) post-intervention. Conversely, Briel 2006 [34] was the only trial that found no significant reduction in antibiotics dispensed within two weeks of the index consultation (full intervention versus limited intervention: 13.5% and 15.7%; adjusted OR 0.86, 95% CI 0.40 to 1.93). DECISION+2 led to fewer patients deciding to use antibiotics immediately after the consultation (immediate versus no or delayed antibiotic use) for ARIs compared with usual care (27.2% versus 52.2%; adjusted RR 0.5, 95% CI 0.3 to 0.7).[37] Little 2013 [38] demonstrated that antibiotic prescribing for predominately acute lower respiratory tract infections (LRTIs) and upper respiratory tract infections (URTIs) was lower in the intervention group compared with controls (36.1% versus 45.3%; adjusted RR 0.69, 95% CI 0.54 to 0.87). Cals 2009 [35] demonstrated a reduction in antibiotic prescribing for patients with suspected LRTI recruited during the winters of successive years (2005 to 2006 and 2006 to 2007) (intervention versus control: 27.4%, 95% CI 25.6% to 36.6% versus 53.5%; 95% CI 43.8 to 63.2; P value < 0.01). Butler 2012 [40] measured a mean 4.2% (95% CI 0.6% to 7.7%; P value = 0.02) reduction (as a percentage of the mean in controls) in the total number of dispensed oral antibiotic items per 1000 registered patients for the year after the intervention practices were exposed to the STAR programme. A non-significant reduction in the decision to immediately use antibiotics was also observed in the pilot trial by Légaré 2011 [42] (-16.0%; P value = 0.08). Welschen 2004 [39] reported significantly reduced antibiotic prescribing rates for symptoms of ARIs (-10.7%, 95% CI -20.3% to -1.0%). In a long-term follow-up [41] of Cals 2009,[35] enhanced communication skills training showed sustained reduction in antibiotic prescribing at 3.67 years mean follow-up (intervention versus

control: 26.3%, 95% CI 20.6% to 32.0 versus 39.1%, 95% CI 33.1% to 45.1%; corrected difference: -10.4%; P value = 0.02). Supplementary material: Table S5.

We graded the quality of evidence as moderate and low for antibiotic prescribing in the short term (less than six weeks) and long term (12 months or longer), respectively. See Summary of findings table 2

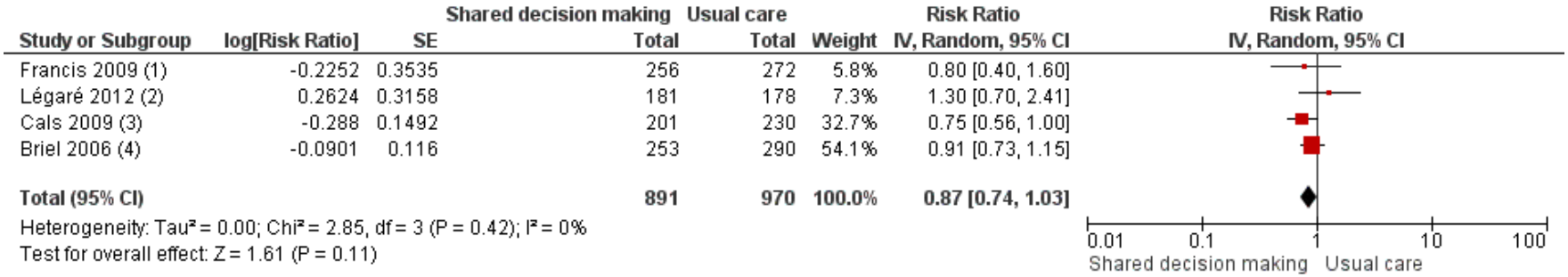
Secondary outcomes

1. Number or rate of patient-initiated re-consultations for unresolved ARI

Six studies reported adjusted effect estimates that we could not combine in a meta-analysis. We extracted data from four studies to calculate a RR adjusted for clustering, and pooled in meta-analysis. The RR compared to usual care was 0.87, 95% CI 0.74 to 1.03; P value = 0.11 (Analysis 1.6; Figure 9).

The proportion of re-consultations for the same illness episode reported in Briel 2006 [34] was 44.7% versus 49.3% (adjusted RR compared to controls 0.97, 95% CI 0.78 to 1.21). The between-group consultation rates in Cals 2009 [35] were 27.9% (95% CI 21.4 to 34.4) and 37.0% (95% CI 30.4 to 43.6); P value = 0.14. Légaré 2012 [37] reported no differences between groups (22.7% versus 15.2%; absolute difference 7.5%; adjusted RR compared to controls 1.3, 95% CI 0.7 to 2.3). Francis 2009 [36] also reported no difference in the odds of re-consulting in primary care during the two weeks after the index consultation (12.9% versus 16.2%; adjusted OR 0.75 (0.41 to 1.38). Butler 2012 [40] found no difference in median re-consultation rates after an index consultation for respiratory tract infections per 1000 registered patients at seven days (-0.65, 95% CI -1.69 to 0.55, P value = 0.446); 14 days (-1.33, -2.12 to 0.74; P value = 0.411); or 31 days (-2.32, 95% CI -4.76 to 1.95; P value = 0.503). Similarly, Little 2013 [38] found the rates of new or worsening symptoms (including re-consultation in less than four weeks or hospital admission) did not differ significantly between groups (adjusted RR compared to controls 1.33, 95% CI 0.99 to 1.74; P value = 0.055). Supplementary material: Table S6.

We graded the quality of evidence as moderate. See Summary of findings table 2.



Footnotes

(1) Reported intra-class correlation co-efficient (ICC) = 0.06. Design effect and effective sample size calculated.
(2) Adjusted for cluster design and baseline values.
(3) Reported intra-class correlation co-efficient (ICC) = 0.01. Design effect and effective sample size calculated.
(4) Reported intra-class correlation co-efficient (ICC) = 0.04. Design effect and effective sample size calculated.

Figure 9: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.6 Number or rate of re-consultations (risk ratio)

2. Incidence of colonisation with, or infection due to, antibiotic-resistant organisms

No studies reported this outcome.

3. Incidence of hospital admission

Six trials reported serious adverse events (SAEs) requiring hospitalisation, although no significant differences between groups were observed. Butler 2012 [40] reported a non-significant difference in the proportion of hospital admissions for possible respiratory tract infections and complications relative to the control group (-1.9%, 95% CI -13.2% to 8.2%; P value = 0.72). Briel 2006 [34] reported that three patients were hospitalised (two patients in the full intervention group versus one in the limited intervention group). Six intervention and two usual care participants were hospitalised in Little 2013 [38] (factorial analysis not reported). Francis 2009 [36] reported seven hospitalisations (intervention = three, control = four). There were no occurrences of SAEs (death or admission to hospital) in Cals 2009 [35]. Cals 2013 [41] reported five hospital admissions of 379 study participants: two patients receiving usual care (four exacerbations of chronic obstructive pulmonary disease (COPD) and one case of pneumonia), one randomised to C-reactive protein testing, and two episodes (pneumonia) in the combined intervention group (factorial analysis data not reported). Supplementary material: Table S7.

4. Incidence of pneumonia

Two studies reported on the incidence of pneumonia. Briel 2006 [34] reported one case of pneumonia in the control group, and Cals 2013 [41] reported two cases of pneumonia in patients receiving a combined intervention (factorial analysis data not reported) and two cases of pneumonia in those receiving usual care. Supplementary material: Table S8.

5. Incidence of acute otitis media complications

No studies reported on this outcome.

6. Mortality due to respiratory illness or similar

One study, Briel 2006 [34], reported a fatal myocardial infarction following pneumonia in an elderly patient receiving a limited (control) intervention.

7. All-cause mortality

No studies reported on this outcome.

8. Measures of patient and caregiver satisfaction

The results from two studies could be pooled, giving an OR compared to controls of 0.86, 95% CI 0.57 to 1.30; P value = 0.47 (Analysis 1.7; Figure 10).

There were no differences observed between intervention and control groups in studies that reported this outcome. Briel 2006 [34] found no difference in scores for patient satisfaction (Patient Satisfaction Questionnaire; score 0 to 70) between intervention and control groups (median 68 out of 70; % patients with 70 out of 70: 47.8% versus 49.0%; adjusted OR 1.00; 95% CI 0.64 to 1.31). Cals 2009 [35] reported no differences in patient satisfaction with the index consultation (% at least very satisfied: 78.7%, 95% CI 72.5 to 84.9 versus 74.4%, 95% CI 68.2 to 80.6; P value = 0.88). In Francis 2009,[36] the proportion of parents that were reported to be satisfied or very satisfied with the consultation were similar between groups (90.2% versus 93.5%; adjusted OR 0.64, 95% CI 0.33 to 1.22). Patient satisfaction (one = very dissatisfied, five = very satisfied) was also high and no between-group differences were observed in Welschen 2004 [39] (adjusted mean difference (MD) -0.03, 95% CI -0.2 to 0.1). Supplementary material: Table S9.

We graded the quality of evidence as low. See Summary of findings table 2.

9. Measures of patient and caregiver satisfaction with the decision reached, decisional conflict and decisional regret

Decisional conflict

One study measured GPs' decisional conflict using the Decisional Conflict Scale (DCS; 1 = low decisional conflict, 5 = very high decisional conflict) and found no difference between the intervention group and controls (MD 3.4, adjusted RR 3.5, 95% CI 0.3 to 38.0) [37]. For patients' decisional conflict scores, the MD was 1.7 and the adjusted RR 0.8, 95% CI 0.2 to 2.4. Supplementary material: Table S10.

Decision regret (patients)

Légaré 2012 [37] observed a clinically insignificant effect between the intervention and control groups on a decision regret measure (0 = very low regret, 100 = very high regret) with

a mean of 12.4 in the intervention group and 7.6 in the control group; adjusted MD 4.8, 95% CI 0.9 to 8.7. Légaré 2011 [42] also reported no difference in the proportion of patients with decisional regret between the study groups (7% in the intervention group versus 9% in the control; adjusted MD -2, 95% CI -12 to 5). Supplementary material: Table S11.

10. Measures of extent of patient involvement in the decision making process

Patient enablement

Three studies reported on patient enablement. Cals 2009 [35] found no difference between intervention and control group scores on the Patient Enablement Instrument (PEI; score 0 to 12) (mean (SD): 3.29 (2.52) versus 3.06 (2.54); P value = 0.70). Francis 2009 [36] found no between-group difference in a modified PEI measuring parent enablement (score 0 to 10; score greater or equal five: 40.2% versus 35.9%; adjusted OR 1.20, 95% CI 0.84 to 1.73). Briel 2006 [34] found weak evidence for higher patient enablement on the PEI (median 8 out of 12; mean (SD) 8.49 (1.98) versus 8.15 (2.03); adjusted MD 0.35, 95% CI -0.05 to 0.75). Supplementary material: Table S12.

11. Measures of treatment compliance or adherence to decision reached

Decision quality

Légaré 2012 [37] found no difference between GPs on a measure of GPs' decision quality (1 = very low quality, 10 = very high quality) (MD -0.2, 95% CI -0.6 to 0.2). The results were similar to the earlier pilot cluster-RCT, Légaré 2011 [42] (MD -0.2, 95% CI -0.34 to 0.89; P value = 0.29). Similarly, there were no differences observed in patients' decision quality in Légaré 2012 [37] (MD 0.0, 95% CI -0.4 to 0.4) and Légaré 2011 [42] (MD 0.1, 95% CI -0.88 to 0.94; P value = 0.57). Supplementary table: Table S13 and Table S14.

Adherence to decision

The only trial to measure adherence to the decision reached found no difference between intervention and control groups (87.7% of patients versus 91.5%; absolute difference of 3.8, adjusted RR 1.0, 95% CI 0.9 to 1.0).[37]

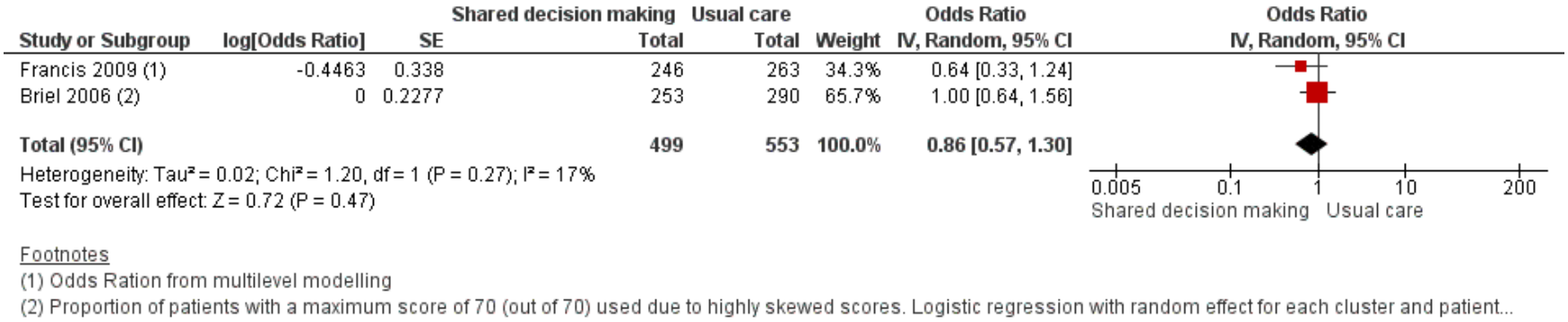


Figure 10: Forest plot of comparison: 1 Shared decision making versus usual care (control), outcome: 1.7 Patient satisfaction with the consultation

Discussion

Summary of main results

Interventions aiming to promote shared decision making in primary care, as the focus or a core component of multi-faceted interventions, significantly reduced antibiotic prescribing for acute respiratory infections by almost 40% compared with usual care in the short term. There was insufficient evidence for sustained reductions in antibiotic prescribing over the longer term. There were no significant differences between groups receiving the intervention or usual care in clinical complications such as re-consultation for the same illness, or patient satisfaction with the consultation. There was also insufficient evidence to assess intervention effects on other clinically adverse or patient and/or caregiver shared decision process outcomes.

Overall completeness and applicability of evidence

A growing number of trials have examined the effect of interventions that aim to facilitate shared decision making, with all studies being conducted in the last 10 years (seven of 10 studies in the last five years), highlighting that shared decision making is a relatively new intervention. All studies included acute upper or lower respiratory tract infection in children and/or adults consulting primary care or academic general practice. Trials were conducted in several high-income European countries and Canada. Applicability of findings to low- and middle-income countries and different cultural and healthcare settings is unknown.

We identified considerable heterogeneity in longer-term prescribing outcomes meta-analysed as risk ratio (see Analysis 1.2), and moderate to substantial heterogeneity in pooled results grouped under each reported effect estimate for the primary outcome (see Analysis 1.3; Analysis 1.4; Analysis 1.5). There was considerable diversity across included studies within each comparison in terms of the population (adults, children, or both), scale and composition of multi-component interventions evaluated, timing of the intervention and follow-up, outcome measures used and statistical techniques. The considerable heterogeneity observed in antibiotic prescribing rates over the longer term may be due to measurement differences in one study [40] (all oral dispensed antibiotic items per 1000 registered patients for the year following exposure of practices to the intervention), or the low number of studies reporting longer-term sustainability of intervention effects. Substantial (although non-significant) heterogeneity apparent in studies reporting an adjusted odds ratio (OR) (see Analysis 1.3; I^2 statistic = 57%; P value = 0.10) may have resulted from the inclusion of one study reporting a statistically non-

significant intervention effect [34], where an unusually low antibiotic prescribing rate was noted (13.5% and 15.7% in the study groups) compared with other studies. Detecting an intervention effect may be difficult in a low prescribing setting. Some heterogeneity in pooled studies reporting an adjusted relative risk (Analysis 1.4; I^2 statistic = 19%; P value = 0.27) may result from true clinical and/or methodological diversity with the non-significant result being simply an artefact of only two studies being available for the comparison. Significant heterogeneity in four studies reporting adjusted risk differences (Analysis 1.5; I^2 statistic = 37; P value = 0.19) is likely due to inherent multiplicity of clinical and methodological factors.

The effect size of the included studies varied considerably, although there was general consistency in the direction of effects. The risk of bias overall in the included studies was low. Interventions varied markedly in the theoretical basis, and the components, scope, mode of delivery and duration. It is not possible, therefore, to identify which intervention components, combinations or modes of delivery most effectively promote shared decisions. Interventions and training were principally targeted at GPs. However, competence in the use of shared decision making was only reported in some trials, with no studies assessing intervention fidelity. Objective patient or clinician measures of adoption of shared decision making (e.g. OPTION [32] were not included in any studies). The usefulness of interventions aimed primarily at patients to help facilitate their role in initiating and making shared decisions remains unknown.

Quality of the evidence

We graded the quality of the evidence as moderate or low for all outcomes. All cluster-level randomised controlled trials (RCTs) used a method of sequence generation aimed at minimising chance between-group imbalance. All study participants (clusters) were randomised after they were enrolled and prior to group allocation to minimise selection bias. Blinding was not possible because of the nature of the interventions. We considered only two studies to have substantial loss to follow-up.[12,37] Altiner 2007 [12] did not conduct an intention-to-treat (ITT) analysis although they explored the effects of differential missing values in cluster-level sensitivity analysis. An ITT analysis was not reported by Légaré 2012.[37]

Pooled studies for the primary outcome, antibiotic prescribing, were limited by the diversity in adjusted effect estimates reported and resulted in a low number of studies in each presented comparison (see Analysis 1.3; Analysis 1.4; Analysis 1.5). This was surmounted by

calculating a risk ratio (RR) (using the design effect to adjust for clustering) for meta-analysis (see Analysis 1.1; Analysis 1.2; Analysis 1.6), which results in some loss of precision, although it is still robust (and more conservative at least). Similarly, meta-analysis could not be performed for several clinically important secondary outcomes due to variance in effect estimates reported or measurement differences, which resulted in only a small number of trials being included for patient satisfaction (see Analysis 1.7). The low number of trials in addition to the presence of considerable heterogeneity in the longer-term reduction in antibiotic prescribing suggests that the overall pooled results and meaningful exploration of heterogeneity was limited and should be interpreted with caution. See Summary of findings table 1.

Potential biases in the review process

Combining trials under a common effect estimate (RR) for antibiotic prescribing in the longer term (≥ 12 months) required us to impute intra-class correlation coefficients for two studies,[40,41] from similar studies, so that the design effect for adjustment of clustering effects could be calculated. The results for these outcomes should be interpreted with caution.

Agreements and disagreements with other studies or reviews

Other systematic reviews have assessed clinician- and/or patient-oriented interventions to influence antibiotic prescribing for acute respiratory infections (ARIs) in primary care.[23,47-52] Meaningful comparisons about the relative effectiveness of studies is limited by the diversity in study designs, interventions and outcome measures. Two reviews concluded that multiple component interventions that provided education to healthcare professionals and patients were most often effective in reducing antibiotic use for respiratory tract infections.[23,51] Multi-faceted interventions and computer strategies aimed at healthcare professionals most effectively reduced antibiotic prescribing in children with upper respiratory tract infections.[48] Provision of patient information alone,[50] or in addition to physician education,[51] appears to offer only moderate or little additional benefit, respectively. However, reviews exclude many recent high quality intervention trials incorporating patient information materials and training explicitly aiming to facilitate shared decision making. Two reviews found that educational interventions directed at parents and/or caregivers were effective in modifying consulting behaviour and antibiotic use for children with ARIs, and may be more successful when they engage children [47,52]. Interventions were also more successful when they were delivered prior to the consultation

and focused on specific symptoms.[47] Several reviews concluded that a reduction in antibiotics was not at the expense of adverse clinical outcomes,[49] or patient satisfaction.[47,49,50] Previous reviews have raised the importance of a patient-centred approach to help patients adopt a more active role in decision making about antibiotics for ARIs,[50] and communication skills training for physicians has been highlighted as a promising intervention element.[51]

Authors' conclusions

Implications for practice

Interventions that aim to facilitate shared decision making reduce antibiotic prescribing for acute respiratory infections (ARIs) in primary care in the short term by a relative risk reduction of almost 40% compared with usual care, without an increase in patient-initiated re-consultations for the same illness or a decrease in patient satisfaction. There is insufficient evidence that the effect may be sustained in the medium to longer term (~ one to three years). Whether the reduction in antibiotic prescribing achieved is sufficient, or sustained long enough, to reverse community-level resistance trends is not known as this was not measured in the included studies. We graded the quality of the evidence as moderate or low for all outcomes. The variety in the interventions and training components studied has important implications for knowing which intervention components should be used in clinical practice, or how best to adapt successful programmes to other primary care environments with different practice characteristics or access to financial and core support resources.

Implications for research

The addition of future trials into this systematic review may allow greater precision of the effects of shared decision making and an opportunity to explore reasons for the heterogeneity of the results. Evaluation of intervention adherence and fidelity (the degree to which the intervention was delivered as intended) should be incorporated into new studies. Further long-term follow-up of included studies would also provide greater certainty regarding the maintenance of intervention effects. Further research should also aim to determine which aspects of these interventions provide the greatest benefit to adapt programme implementation and uptake in diverse clinical settings. Research will also need to establish the link between a reduction in antibiotic prescribing for ARIs in primary care and the reversal in community-level antibiotic-resistance trends, to validate the usefulness and sustainability of programmes.

Furthermore, while the interventions in studies are principally aimed at developing general practitioners' (GPs') communication skills to facilitate shared decision making, there appears to be scope to pursue ways of involving healthcare consumers in the design, planning and delivery of interventions to promote shared decision making for ARIs in primary care. Finally, although not relevant to the present review, the cost-effectiveness of establishing shared decision making training programmes in primary care to reduce antibiotic use for ARIs requires further research interest.

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Contributions of authors

Tammy Hoffmann (TH) conceived the original idea for the review. Peter Coxeter (PC) was responsible for drafting the protocol.TH and Chris Del Mar (CDM) contributed content and methodological expertise and provided advice and guidance on the development of the draft protocol and final editing. Elaine Beller (EB) provided statistical advice and guidance. Leanne McGregor conducted independent screening (titles/abstract and full text) and data extraction.

Declarations of interest

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Supplementary material

Published with article presented in Chapter 4

Table S1: Characteristics of included studies

Altiner 2007

Methods	Study design: cluster-randomised controlled trial Unit of randomisation: general practitioner (GP) Trial duration: November 2003 to March 2005 Recruitment: 2036 GPs from 9 regions in North-Rhine and Westphalia-Lippe, Germany, invited to participate (blinded to the primary outcome); of 239 GPs willing to participate and receiving baseline materials, 104 completed reliable baseline study documentation and were randomised (10 practice partners randomised as pairs) into intervention (GPs = 52, patients = 1389) and control groups (GPs = 52, patients = 1398) Methods of data collection: GPs recorded all consecutive and eligible patients during each documentation period on study specific paper documentation Data collection time points: 3 documentation intervals of 6 weeks each: baseline (before randomisation), and 6 weeks and 12 months post-intervention Length of follow-up: 12 months
Participants	GPs documented all consecutive and eligible patients: ≥ 16 years of age with an initial episode of acute cough (without prior episode < 8 weeks) and could comprehend German Exclusion: patients with underlying chronic lung diseases (e.g. asthma, chronic obstructive pulmonary disease), immune deficiency or malignant diseases
Interventions	Brief intervention name: complex, peer-led, educational intervention Recipients: GPs and patients (passive) Providers: GP peers were trained to provide (in 3 sessions) the outreach visits in clinics during normal working hours (methods of training these GP peers were not specified) Health professional components: focused on antibiotic 'misunderstanding' during a consultation, and aimed to motivate GPs to change attitudes to communication and empower patients.

	Peers addressed GP beliefs and attitudes by exploring and evaluating GPs 'opposite' motivational background using a standardised dialogue script and communication techniques derived from the elaboration likelihood model. Aspects of the intervention were also informed by previous qualitative work Patients: waiting room poster and leaflet focusing on the patients' role within the antibiotic misunderstanding (e.g. GP perceptions that patients expect an antibiotic) and also brief evidence-based information about acute cough and antibiotics to enable patients to raise and clarify issues and make a joint decision about antibiotic use with their doctor Materials: waiting room poster and leaflet (patient only); script used by GP peers Mode of delivery: face-to-face (GPs) and waiting room posters and leaflets (patients) Duration and intensity: 1 peer outreach visit per GP (duration not specified) Comparator: nil active comparator; GPs provided usual care	
Outcomes	Primary: rate of antibiotic prescriptions per acute cough and by GP (study specific paper documentation) Secondary: nil	
Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: no Trial registration: yes Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Program-generated complete randomisation list
Allocation concealment (selection bias)	Low risk	Not described. However, GPs recruited prior to randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (complex peer-led educational intervention)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participating GPs sent data to researchers. Each patient was assigned a unique identification number that could be connected with the patient only by the participating GP
Incomplete outcome data (attrition bias) All outcomes	High risk	Randomised: 104 GPs (intervention = 52, 1389 patients; control = 52, 1398 patients) 6 weeks post-intervention: 86 GPs (intervention = 42 (80%), patients = 1021; control = 44 (84%), patients = 1143) 12 months post-intervention: 61 GPs (intervention = 28 (54%); 787 patients; control = 33 (63%); 920 patients) 17% (18/104) dropped out at 6 weeks and 41% (43/104) by 12 months (reasons for GPs' exclusion from analysis: poor data quality or did not return data) Cluster-level sensitivity analysis performed to explore effect of differential missing values
Selective reporting (reporting bias)	Low risk	All indicated results reported. Prospective trial registration: Projektdatenbank Versorgungsforschung NRW, ID: 90/34/CHANGE
Other bias	Unclear risk	Sample size (power) calculation: yes. Sample size calculated on number of patients to detect a 10% difference in 6-month prescription rates (50% control, 40% intervention). Allowing for 20% drop-out rate, it was estimated 200 GPs would be required to contribute 20 patients during each observation period (i.e. 4000 at each of the 3 documentation periods) ITT or per protocol analysis: no, all analysis (with exception of sensitivity analyses) included only general practices with complete follow-up Large baseline difference found in antibiotic prescription rates between intervention and control groups (36.4% versus 54.7%) (unadjusted and adjusted analysis performed)

		GPs were not monitored during the trial period and may have under-reported patients who received an antibiotic Government regulatory change during study to exclude OTC medicines from reimbursement by German statutory health insurance funds may have increased antibiotic prescribing decisions to minimise patient out-of-pocket cost Generalised estimating equation (GEE) models applied Intraclass correlation (coefficient): 0.20

Briel 2006

Methods	Study design: cluster-randomised controlled trial Unit of randomisation: general practitioner (GP) Trial duration: January to May 2004 Recruitment: 345 eligible GPs (criteria undefined) from 2 Swiss cantons (Basel-Stadt and Aargau), where self-dispensation of drugs is not allowed. 30 GPs (providing written consent by 1 December 2003) were randomised to limited or full intervention groups (15 GPs each); the remaining 15 GPs (providing written consent by 1 January 2004) formed the non-randomised control group Methods of data collection: baseline data for eligible GPs obtained from the registry of the Swiss Medical Association; GPs recorded patient baseline data; medical students conducted standardised patient follow-up interviews at 7 and 14 days by telephone; pharmacists faxed all prescriptions with study labels to the study centre Length of follow-up: 14 days
Participants	GPs recruited all consecutive and eligible adult patients: ≥ 18 years with symptoms of acute infections of the respiratory system (first experienced within the previous 28 days; including common cold, rhinosinusitis, pharyngitis, exudative tonsillitis, laryngitis, otitis media, bronchitis, exacerbated COPD or influenza) *Exclusion:* patients with pneumonia, not fluent in German, with intravenous drug use or psychiatric disorders, and not available for phone interviews or unable to give written informed consent

Interventions	Brief intervention name: patient-centred communication training Recipients: GPs Providers: unclear Health professional components: evidence-based guidelines (developed by 3 trial authors based on existing US guidelines, adapted to local conditions and reviewed by local experts) presented as a booklet and in a 2-hour interactive seminar, plus a 6-hour patient-centred communication seminar in small groups (number not defined) and 2 hours of personal feedback by phone prior to the start of the trial. Training aimed to teach GPs how to understand and modify patients' concepts and beliefs about the use of antibiotics for ARIs. Physicians were taught to practice elements of active listening, to respond to emotional clues and tailor information given to patients. GPs identified patients' attitudes and readiness for behaviour change using a theoretical model (Prochaska and DiClemente 1992) Patient components: nil Materials: evidence-based guidelines for the treatment of ARIs distributed as a booklet (http://www.bice.ch/publications/reports) Mode of delivery: booklet and face-to-face small-group interactive patient-centred communication seminar Duration and intensity: GPs attended 1 x 2-hour interactive evidence-based guidelines seminar and 1 x 6-hour small group interactive patient-centred communication seminar Comparator 1 (Limited intervention): evidence-based guidelines presented as a booklet and in a 2-hour interactive seminar alone Comparator 2 (Non-randomised control): usual care (data not extracted)
Outcomes	Primary: antibiotic prescriptions dispensed by pharmacists < 2 weeks following initial consultation (prescriptions with study labels faxed by pharmacists to the study centre) Secondary: rates of different diagnoses of respiratory infections (GP records) Adherence to guidelines for antibiotic prescription (GP records) Days with restrictions from respiratory infection (patient follow-up interview at 7 and 14 days) Days off work (patient follow-up interview at 7 and 14 days)

	Re-consultation rates (patient follow-up interview at 7 and 14 days) Patient satisfaction (Patient Satisfaction Questionnaire; patient follow-up interview at 7 and 14 days) Patient enablement (Patient Enablement Instrument; patient follow-up interview at 7 and 14 days) Other: serious adverse events (independent monitoring board review of serious adverse events that occurred < 28 days of study enrolment)	
Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: no Trial registration: not stated Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated list created by an independent institution
Allocation concealment (selection bias)	Low risk	Allocation to either intervention was concealed. However, method not stated. However, GPs recruited prior to randomisation
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding of general practitioners and trial staff reported. As this trial had 3 arms (2 intervention arms where the intervention in each involved a seminar and distribution of evidence guidelines; 1 usual care arm), it is possible that the GPs in the intervention arms would not have known which intervention group they were in
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Medical students, blinded to the goal of the trial, were trained to conduct standardised follow-up interviews at 7 and 14 days by phone Prescriptions with study labels faxed by pharmacists to the study centre were checked and entered into the database by a person blinded to the intervention group

		Trial authors assessed adherence of all prescriptions to guidelines independently and blinded to the intervention group
Incomplete outcome data (attrition bias) All outcomes	Low risk	GPs randomised into limited intervention (GPs = 15; patients = 293) and full intervention groups (GPs = 15; patients = 259); 15 GPs (285 patients) participated as non-randomised controls (data not extracted). All GPs completed the trial. There were 290, 253 and a convenience sample of 93 patients (stratified by physician), respectively, interviewed at 7 days; and 287, 245 and 92 patients interviewed at 14 days. Reasons for loss to follow-up reported
Selective reporting (reporting bias)	Low risk	All indicated results reported. Trial registration or published trial protocol not stated
Other bias	Unclear risk	Sample size (power) calculation: yes ITT or per protocol analysis: ITT Intraclass correlation (co-efficient) reported: 4.0% and a design effect of 1.6% Low study baseline prescribing rates – full intervention (13.5%), limited intervention (15.7%) and non-randomised control (21.4%) Highly motivated GPs: recruitment coincided with introduction of a new nation-wide computer-based reimbursement system and due to increased workload participating GPs considered to be highly motivated

Butler 2012

	Study design: cluster-randomised controlled trial Unit of randomisation: general practices Trial duration: conducted during 2007 and 2008 Recruitment: 212 general practices approached at random from 454 eligible practices in Wales, UK. 102 practices expressed interest to participate; 70 recruited; 68 practices (˜480,000 patients) randomised to intervention or control groups (34 each)

	Methods of data collection: routine administrative systems (see 'Outcomes') Data collection time points: total numbers of dispensed oral antibiotic items (primary) and hospital admissions for possible RTIs and their complications (secondary): rate per 1000 patients for the year after the intervention practices were exposed to the intervention; re-consultation for RTIs: (secondary; 7, 14 and 31 days after initial consultation). Cost data not extracted Length of follow-up: 12 months
Participants	Clinicians (general practitioners (GPs) and nurse practitioners) and all patients registered with and consulting a participating general practice in Wales (practice list)
Interventions	Brief intervention name: Stemming the Tide of Antibiotic Resistance (STAR) educational programme: multifaceted flexible blended learning approach to continuing education for clinicians Recipients: clinicians (GPs and nurse practitioners) Providers: web-based modules and practice-based seminar led by a facilitator Health professional components: the programme is a blended learning experience, and based on Social Learning Theory to develop GPs sense of importance about change (the 'why' of change) and confidence in their ability to achieve change (the 'how' of change). The intervention consist of 7 parts (5 online, 1 face-to-face and 1 facilitator-led practice-based seminar): case-scenarios and updated summaries of research evidence and guidelines; reflections on clinical judgement on antibiotic prescribing; a facilitator-led practice-based seminar presenting regional, local and practice-level antibiotic prescribing and resistance data; novel communicative consulting skills and information exchange based on motivational interviewing; personal reflections on clinical practice; web-based forum to share experiences and views; and a booster module completed 6 to 8 months after completion of the initial training to reinforce previously outlined communication skills. GPs had to complete each online learning component before the software would allow them access to the next. The intervention was flexible to allow GPs to access online components and try out new skills with patients at their convenience Patient components: nil Materials: web-based materials

	Mode of delivery: interactive web-based modules (including online videos in addition to a facilitator-led practice-based seminar Duration and intensity: not specified Comparator: usual care	
Outcomes	Primary: total number of dispensed oral antibiotic items per 1000 registered patients for the year after practices were exposed to the STAR programme (Prescribing Audit Reports and Prescribing Catalogues; www.nhsbsa.nhs.uk/prescriptions) Secondary: hospital admission rates for possible RTIs and their complications per 1000 registered patients for the year after practices were exposed to the STAR programme.(Patient Episode Database for Wales); and practice re-consultation rates (for patients with RTIs, practice re-consultation rates were identified using diagnostic READ codes recorded by the general practitioner over 7, 14 and 31 days after an initial consultation) Costs data not extracted	
Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: yes Trial registration: yes Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation was conducted once all practices were recruited and all participating physicians had provided written consent. Dynamic block allocation was used to achieve balance between groups of practices for the potential confounders of previous rate of antibiotic dispensing (averaged over the past year), practice size (number of whole time equivalent staff at recruitment), and proportion of clinicians in the practice registered for the study. The practices were divided into 3 sets of 24, 22 and 22 practices; within each set we generated all possible allocations into 2 groups and selected the 1000 allocations within each set with the best balance with respect to the specified

		confounders. The independent statistician on the trial steering committee selected 1 allocation at random for each set and randomly assigned intervention or control to the 2 groups in each set to construct the final allocation
Allocation concealment (selection bias)	Low risk	Clinicians and researchers were blinded to group allocation until after randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (multifaceted intervention programme)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data on antibiotic dispensing, hospital admissions and re-consultations were collected through routine administrative systems that were not influenced by the study research process
Incomplete outcome data (attrition bias) All outcomes	Low risk	68 practices (˜480,000 patients) randomised to intervention (34 practices; 137 GPs, 2 nurse practitioners) or control (34 practices; 122 GPS, 2 nurse practitioners) groups. 2 practices (one in each group; including 12 intervention GPs and 7 control GPs) withdrew after randomisation but were included in the ITT analyses
Selective reporting (reporting bias)	Low risk	All indicated results reported. Published trial protocol available
Other bias	Low risk	Sample size (power) calculation: yes ITT or per protocol analysis: ITT analysis for primary outcome

Cals 2009

Methods	Study design: cluster-randomised controlled trial (factorial design). Unit of randomisation: general practices (cluster of 2 general practitioners (GPs) per practice) Trial duration: conducted during the winters of 2005 to 2006 and 2006 to 2007 Recruitment: 54 general practices within a large suburban region of the Netherlands were assessed for eligibility; 20 eligible general practices (with 2 participating GPs per practice) were randomised into groups of 10 practices per intervention (resulting in 4 trial arms of 5 general practices and 10 GPs):

	- use of C-reactive protein (CRP) testing; - training in enhanced communication skills; - use of CRP and training in enhanced communication skills; - control (usual care) Methods of data collection: antibiotic prescribing and re-consultation data obtained from patient medical records. Patients rated symptoms (cough, phlegm, shortness of breath, disturbance of daily activities, sleeping problems and generally feeling unwell), satisfaction and enablement, on a 28-day daily diary validated for use in a RCT on management of LRTI in primary care Data collection time points: index consultation and 28-day follow-up
Participants	General practitioners recruited sequential eligible adults within regular consultation hours during the winters of 2005 to 2006 and 2006 to 2007 Eligibility: suspected lower respiratory tract infection (LRTI) with a cough lasting < 4 weeks together with1 focal and 1 systemic symptom
Interventions	Brief intervention name: enhanced communication skills training Recipients: GPs Providers: seminars led by a moderator Health professional components: enhanced communication skills training involved 1 x 2-hour training seminar at a central location, preceded and followed by consulting with simulated patients in routine surgeries and peer-review of transcripts. The moderator-led seminar on shared decision making (within 1 week of simulated patient consultation) comprised GPs' reflection on simulated patient transcript, current views and insights on LRTI (highlighting contrast between research and practice), outline of elicit-provide-elicit framework (elicit patient's main worries and expectations and conveying the balance of possible antibiotic benefits and harms, provide information relevant to the patients' individual understanding and interest, and elicit patients' interpretation about what has been said and done and discusses implications for help seeking behaviour), videos presenting practice-based examples and GPs identifying specific aspects during their consultations that need most attention Patient components: nil

	Materials: desk reminder for GPs Mode of delivery: face-to-face seminar and simulated patient consultations with peer-review of transcripts Duration and intensity: 1 x 2-hour moderator-led training seminar; pre- and post-seminar simulated patient consultations with peer-review of transcripts Comparator 1: C-reactive protein point of care testing (date not extracted) Comparator 2: enhanced communication skills training plus C-reactive protein point of care testing (date not extracted) Comparator 4: usual care (Dutch guidelines for managing acute cough, including diagnostic and therapeutic advice for lower respiratory tract infection are distributed to all GPs in the Netherlands)	
Outcomes	Primary: antibiotic prescribing in the index consultation (medical records) Secondary: antibiotic prescribing during 28 days' follow-up (medical records) Re-consultation (medical records) Clinical recovery data not extracted Patients' satisfaction (Likert scale; 28-day daily diary) Patients' enablement (Patient Enablement Index; 28-day daily diary)	
Notes	Funding: yes Conflict of interest: none declared Published trial protocol: yes Trial registration: yes Ethics approval: yes Main comparator reported in this review: communication skills training (n = 201) versus no communication skills training (n = 230)	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	General practices randomised into 2 groups of 10 practices per intervention, balanced for

		recruitment potential, resulting in the 4 trial arms. The balancing factor used for randomisation was the amount of GP's consultation time (expressed as full time equivalent (FTE)) that the practice was contributing to the study (which equated to between1 and 2 FTEs for clinical contact time. The randomisation was balanced for those with 1.5 or less FTEs and those with more than 1.5 FTEs
Allocation concealment (selection bias)	Low risk	All practices and general practitioners were recruited before randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (due to the nature of the intervention)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 practices (40 GPs) randomised to each of the 4 trial arms (5 practices, 10 GPs each) and recruited 431 patients. 37 GPs completed the trial (3 left on maternity leave in the enhanced communication skills group). All patients (100%) had data for the primary outcome, 90% (mean) had 28-day diary data For the communication skills training group (10 GPs, 84 patients), there was 100% prescribing data and 88% returned diaries.
Selective reporting (reporting bias)	Low risk	All indicative results reported. Published study protocol. Prospective trial registration
Other bias	Low risk	Sample size (power) calculation: yes ITT or per protocol analysis: the primary analysis was ITT

Cals 2013

Methods	Study design: 3.5 year follow-up of a cluster-randomised controlled trial (factorial design) (**Cals 2009**) Trial duration: 3.5 years (mean 3.67 years) Recruitment: patients recruited in the winter periods from September 2005 until March 2007 (**Cals 2009**), were observed until July 2010

	Methods of data collection: medical records Data collection time points: recorded consultations for RTI from original 28-day follow-up period until July 2010 (follow-up period); recorded consultation for RTI for the exact same period preceding the consultation in which the patient was recruited in the original trial (baseline period). Deceased patients and patients that moved practices and whose medical records could not be retrieved were excluded Length of follow-up: mean 3.67 years	
Participants	General practices: see **Cals 2009** Patients: of the original 431 patients enrolled in the trial, 379 patients (87.9%) had accessible medical records for the follow-up period. Only data for the enhanced communication training (178) versus no enhanced communication skills training (201) extracted	
Interventions	See **Cals 2009**	
Outcomes	Primary outcome: average number of episodes of RTIs during the follow-up period for which patients consulted their physician per patient per year (PPPY) and the proportion of these episodes that resulted in an antibiotic prescription Secondary outcome: nil	
Notes	Funding: yes Conflict of interest: RH received travel/lecture funds from Axis-shield (Norway) and Orion Diagnostica (Finland), both manufacturers of C-reactive protein devices Trial registration: yes Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	See **Cals 2009**
Allocation concealment (selection bias)	Low risk	See **Cals 2009**
Blinding of participants and personnel (performance bias) All outcomes	High risk	See **Cals 2009**
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were extracted, by 2 researchers, from the patients' medical records system. No mention if these researchers were blind to the practices' original allocation

Incomplete outcome data (attrition bias) All outcomes	Low risk	379 of 431 patients enrolled in the original trial (87.9%) had accessible medical records for the follow-up period
Selective reporting (reporting bias)	Low risk	See **Cals 2009**
Other bias	Low risk	Sample size (power) calculation: see **Cals 2009** ITT or per protocol analysis: see **Cals 2009**

Francis 2009

Methods	Study design: cluster-randomised controlled trial Unit of randomisation: general practices Trial duration: October 2006 to April 2008 Recruitment: half of all general practices from 9 local health boards in Wales (n = 147) were randomly selected to be sent study information (the other half were provided information about a related RCT conducted in parallel); 49 returned a practice agreement and were randomised. 4 primary care research networks in England also recruited practices; 34 returned practice agreement and were randomised. All randomised practise (83) were allocated to intervention (41 practices; 30 recruited patients; patients = 274) or control (42 practices; 31 recruited patients; patients = 284) Methods of data collection: baseline data (age, duration of illness, symptoms) collected by GPs. Follow-up via a telephone administered questionnaire (or self-completion questionnaire contact unsuccessful by telephone) with child's parent or guardian Data collection time points: index consultation and 14 days after recruitment Length of follow-up: 14 days
Participants	Participating clinicians recruited sequential eligible children (6 months to 14 years) consulting with a respiratory tract infection (cough, cold, sore throat, earache for 7 days or less) and their parents *Exclusion:* children with asthma and those with serious ongoing medical conditions such as malignancy or cystic fibrosis
Interventions	Brief intervention name: interactive booklet on respiratory tract infections in children for use within the consultation and provided as a take home resource Recipients: parents and clinicians

	Providers: not stated Health professional components: the online training described the content and aims of the booklet, and encouraged its use within the consultation to facilitate the use of certain communication skills, mainly exploring the parent's main concerns, asking about their expectations, and discussing prognosis, treatment options and any reasons that should prompt re-consultation Patient components: use of the booklet in the consultation and as a take home resource Materials: 8-page interactive booklet (see www.whenshouldiworry.com) Mode of delivery: 8-page interactive booklet and online training for clinicians in use of the booklet Duration and intensity: not stated Comparator: usual care (clinicians were asked to conduct consultations in usual manner)
Outcomes	Primary: re-consultation (primary or secondary care) during the 2 weeks after the index consultation (telephone administered questionnaire) Secondary: antibiotic prescriptions (telephone administered questionnaire) Antibiotic consumption (telephone administered questionnaire) Future consulting intention (telephone administered questionnaire) Parental satisfaction with the index consultation (5-point Likert; telephone administered questionnaire) Parental enablement (modified Patient Enablement Instrument; telephone administered questionnaire) Perception of the usefulness (value) of the information received during the index consultation (5-point Likert; telephone administered questionnaire) Parental reassurance (3-point Likert; telephone administered questionnaire)
Notes	Funding: yes Conflict of interest: none disclosed

	Published trial protocol: yes Trial registration: yes Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Practices were randomised by a statistician using block randomisation with random block sizes and stratification by practice list size, antibiotic prescribing rate for 2005, and country
Allocation concealment (selection bias)	Unclear risk	It is reported that practices were randomised after agreeing to take part, but no other details are provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (training and use of an interactive booklet for use within consultations and as a take home resource)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Telephone interviewers were blinded to treatment group and asked to record any subsequent unblinding of allocation (e.g. parent talking about receiving a booklet). Interviewers reported becoming aware of participants treatment group in 34/509 (6.7%) of interviews
Incomplete outcome data (attrition bias) All outcomes	Low risk	83 practices were randomised to intervention (41) or control (42) groups; 61 practices, 30 intervention and 31 control practices, recruited 274 and 284 patients, respectively. Primary outcome data were available for 256 patients (93%) in the intervention group (246 completed telephone interviews, 10 postal questionnaire returned) and 272 (96%) control group patients (262 completing telephone interviews, 9 postal questionnaires returned)
Selective reporting (reporting bias)	Low risk	All indicted outcomes reported. Published trial protocol
Other bias	Low risk	Sample size (power) calculation: yes ITT or per protocol analysis: primary analysis was ITT

Little 2013

Methods	Study design: cluster-randomised controlled trial (factorial design) Unit of randomisation: general practices Trial duration: October 2010 to May 2011 Recruitment: all general practices (n = 440) in the localities of study centres were approached, and all clinicians (and nurse prescribers in the UK) in eligible practices who prescribed antibiotics for respiratory tract infections were invited to participate Eligibility: practices that had not previously used interventions to reduce antibiotic prescribing and could include > 10 patients at baseline audit. Networks of at least 2 practices were selected separately in Antwerp (Belgium), Barcelona (Spain), Cardiff (Wales), Łódź (Poland), Southampton (UK), Szczecin (Poland), Utrecht (Netherlands) and the Spanish Society of Family Medicine (Spain) to ensure a range of cultures, languages and regions of Europe (north, south and east) were represented). Of the 259 eligible practices enrolled; 246 were randomised to usual care (n = 61), training in the use of a C-reactive protein (CRP) test at point of care (n = 62), training in enhanced communication skills (n = 61), or in both CRP and enhanced communication skills training (n = 62) Methods of data collection: case report forms (index consultation and follow-up) Data collection time points: index consultation and follow-up (until resolution of symptoms)
Participants	General practitioners (GPs and nurse prescribers in the UK) who prescribed antibiotics for RTIs consecutively recruited up to the first 30 patients with LRTI and up to the first 5 with URTI presenting at each practice. Eligible patients were ≥ 18 years of age, attending a first consultation for acute cough of up to 28 days' duration or what the clinician believed to be an acute LRTI as the main diagnosis, despite cough not being the most prominent symptom; and diagnosis judged by the physician to be an acute upper respiratory tract infection (e.g. sore throat, otitis media, sinusitis, influenza and coryzal illness) *Exclusion:* patients with a working diagnosis of a non-infective disorder (e.g. pulmonary embolus, heart failure, oesophageal reflux, or allergy); use of antibiotics in the previous month; inability to provide informed consent (e.g. due to dementia, psychosis or severe depression); pregnancy; and immunological deficiencies. Pneumonia was not an exclusion criterion

Interventions	Brief intervention name: enhanced communication skills training Recipients: GPs Providers: n/a Health professional components: training focused on the gathering of information on patients' concerns and expectations; exchange of information on symptoms, natural disease course and treatments; agreement of a management plan, summing up and providing guidance about when to re-consult. Physicians were provided with an interactive booklet to use during consultations that included information on symptoms, use of antibiotics and antibiotic resistance, self-help measures, and when to re-consult. The training was supported by video demonstrations of consultation techniques. The Internet modules and materials were translated into the relevant national language and mainly addressed lower respiratory tract infections, although many of the issues were relevant to all respiratory tract infections Patient components: interactive booklet used within consultations Materials: interactive booklet for use within consultations Mode of delivery: Internet training supported by video demonstrations of consultation techniques Duration and intensity: not described Comparator: 1. Usual care 2. Training in use of C-reactive protein (CRP) test at point of care (data not extracted for this review) 3. Both CRP and enhanced communication skills training (data not extracted for this review)
Outcomes	Primary: antibiotic use (index consultation; case-report form) Secondary: new or worsening symptoms defined as re-consultation for new or worsening symptoms < 4 weeks, new signs or hospital admission (review of medical notes) Symptom severity and duration defined as the severity of symptoms in the 2 to 4 days after seeing the physician (case report form; 0 = no problem to 4 = severe problem)

Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: no Trial registration: yes Ethics approval: yes ITT or per protocol analysis: ITT analysis	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation of practices was done by 2 study authors, and was achieved by computer generation of random numbers, stratified by network. Minimisation was applied, on the basis of the proportion of patients prescribed antibiotics from the baseline audit, the number of participating physicians per practice, and the number of patients recruited
Allocation concealment (selection bias)	Low risk	Physicians and patients were unaware of initial group allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (due to the nature of the intervention)
Blinding of outcome assessment (detection bias) All outcomes	High risk	GPs recorded data on a case-report from, during the index consultation
Incomplete outcome data (attrition bias) All outcomes	Low risk	259 practices enrolled and provided baseline data (6771 patients); 13 practices recruited < 10 patients each) were excluded Remaining were 246 practices randomised to CRP (62), enhanced communication training (61), both interventions combined (62), or usual care (61) Antibiotic prescription documentation was available for 58 CRP practices (1062 patients), 55 (90%) enhanced communication skills practices (1170 patients), 62 combined intervention practices (1162 patients) and 53 (87%) usual care practices (870 patients). Reasons for

		exclusion were reported as recruiting no patients
Selective reporting (reporting bias)	Low risk	All indicated outcomes are reported
Other bias	Low risk	Sample size (power) calculation: not stated ITT analysis: yes

Légaré 2011

Methods	Study design: cluster-randomised controlled trial (pilot) Unit of randomisation: family medicine groups (FMGs) Trial duration: during November 2007 and March 2008 Recruitment: 24 FMGs (group of family physicians who work closely with nurses to offer family medicine services to registered individuals) from the greater urban area of Quebec City, Canada, were invited to participate; 4 participating FMGs were randomised either to a group immediately exposed to the DECISION+ program (n = 2) or to a control group which exposure to DECISION+ program was delayed for 6 months (n = 2) Methods of data collection: self-administered questionnaire completed following the consultation at each time point Data collection time points: baseline, following exposure of the intervention group to DECISION+ (˜ 6 months), and following delayed exposure of DECISION+ to controls (˜ 12 months) Length of follow-up: 12 months
Participants	Eligible general practitioners (no previous participation in an implementation trial of SDM and planned to remain in clinical practice for the trial duration) recruited eligibility patients consulting their GP for an ARI: no age restriction, patients or their guardians had to be able to read, understand and write French and had to give informed consent to participate in the trial Exclusion: patients with a condition requiring emergency care. A research professional waited in the FMG's waiting room and recruited patients of enrolled FPs during walk-in clinic hours; 15 patients were recruited per GP: 5 at baseline, 5 after the GPs in the experimental group were exposed to DECISION +, and 5 after the FPs in the control group were exposed to DECISION+

Interventions	Brief intervention name: DECISION+ Recipients: GPs Providers: principal investigators (or co-trainers) Health professional components: DECISION+ is made up of 3 main components 1. Interactive workshops addressed the probability of bacterial versus viral ARIs in primary care, evidence of the benefit/risk of the various treatment options, risk communication techniques and strategies for fostering patient participation in the decision making process. Workshops included videos of simulated patient-GP consultations for each ARI and distinguished 2 approaches (usual care or SDM), and exercises to facilitate group discussion about facilitators and barriers to SDM. GPs were trained to use decision support tools (though video examples and group exercises) developed for each of the 4 targeted ARIs (rhinosinusitis, pharyngitis, bronchitis and acute otitis media) and 1 integrating all 4 ARIs 2. Reminders of expected behaviours: a reminder printed on a letter-sized piece of paper emphasised the use of the decision support tools, reiterated the expected SDM-related behaviours, and highlighted new studies relevant to the pilot trial topics (e.g. new evidence on the risks and benefits of antibiotics). These reminders were mailed to GPs between each workshop. A second reminder was postcards that participants had written to themselves in the last workshop to remind themselves of what they needed to implement in their practice. The research team collected the postcards and mailed them 6 to 8 weeks later 3. Feedback to GPs on the agreement between their decisional conflict scores and that of their first 5 patients Patient components: decision support tools Materials: a booklet summarising the content of the workshop and decision support tools was developed for physician participants and training manuals for the co-trainers Mode of delivery: interactive workshops led by 2 study principal investigators (or co-trainers) and conducted face-to-face in a group format, and using videos and group exercises Duration and intensity: DECISION+: 3 x 3 3-hour interactive workshops, reminders and feedback conducted over a 4- to 6-month period

	Comparator: Usual care (delayed exposure to the DECISION+ intervention)
Outcomes	Primary: decision about using antibiotics (immediate use, delayed use or no use) (GP/patient; self-administered questionnaire) Secondary: Perception of the quality of the decision (GP/patient; single item on a 10-point Likert scale; self-administered questionnaire) Decisional conflict (GP/patient; Decisional Conflict Scale) Patients' intention to engage in SDM in future consultations concerning antibiotics for ARIs (3-item, 7-point Likert scale; self-administered questionnaire) GPs' intentions to engage in SDM and comply with clinical practice guidelines regarding prescribing antibiotics for ARIs (3-item, 7-point Likert scale) Decision Regret Scale (patients; telephone interview; 2 weeks following consultation) Perception of health changes since the consultation (patients; telephone interview; 2 weeks following consultation) Number of prescriptions filled by patients covered by Quebec's public drug insurance plan (Regie de l'Assurance-Maladie du Quebec medication claims database) (during the 3 months preceding baseline and during the 3 months after FPs in the experimental group were exposed to DECISION+) Script concordance test (probes whether respondents' knowledge is efficiently organised to take appropriate clinical action by placing respondents in written, but authentic, clinical situations in which they must interpret data to make decisions. It measures the concordance between respondents' scripts and the scripts of a panel of experts (administered to GPs at each data collection point)
Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: yes Trial registration: not reported Ethics approval: yes
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A biostatistician simultaneously randomised all FMGs using Internet-based software
Allocation concealment (selection bias)	High risk	A biostatistician allocated FMGs to groups using Internet-based software. There was concealed allocation of the Family Medicine Groups, but not the family physicians
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (multiple-component, continuing professional development programme in shared decision making)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Codes were attributed to the trial groups and the bio-statistician analysed the data blindly. Team members accessed the codes only after having completed the analyses and interpreting the results
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 FMGs randomised to intervention (2; GPs = 18; patients = 245) or control groups (2; GPs = 15; patients = 214). 3/33 (9%) GPs dropped out of the trial 20/245 patients in the intervention group and 14/214 controls could not be contacted over the 2-week follow-up
Selective reporting (reporting bias)	Low risk	All indicated outcomes reported. Published trial protocol
Other bias	Low risk	Sample size (power) calculation: no Primary analysis was ITT

Légaré 2012

Methods	Study design: cluster-randomised controlled trial Unit of randomisation: family practice teaching units Trial duration: July 2010 to April 2011 Recruitment: the network of 12 family practice teaching units in 6 regions of Quebec, Canada, were randomised to intervention (6) or control (6) groups Methods of data collection: following the consultation, patients and GPs independently completed self-administered questionnaires (primary and secondary outcomes). 2 weeks later, a telephone follow-up interview was conducted by a research assistant (secondary outcomes)

	Data collection time points: immediately following consultation and 14 days
Participants	GPs, including physician teachers and residents, who provide care in the walk-in clinics of the 12 family practice teaching units. GPs participating in the pilot trial (Légaré 2011) or those not expecting to practice in the teaching unit during the trial period were excluded. Patients with symptoms suggestive of an ARI were recruited by a research assistant in the waiting room prior to consultation with a physician. Eligible patients were adults (and children who were accompanied by a parent/legal guardian) with a diagnosis of ARI (e.g. bronchitis, otitis media, pharyngitis or rhinosinusitis) and for which the use of antibiotics was subsequently considered either by the patient or physician during the visit. The patient, parent or legal guardian had to be able to read, understand and write French
Interventions	Brief intervention name: DECISION+2 shared decision making program Recipients: GPs Providers: trained facilitators Health professional components: an online tutorial comprised of 5 modules addressing key components of the clinical decision making process about antibiotic treatment for ARI in primary care: introduction to shared decision making and ARIs, estimating diagnostic probabilities for ARIs, therapeutic options, effective strategies to communicate risk and benefits, identify patients' values and preferences; and use of decision support tools that promote shared decision making. Participants had 1 month to complete the online tutorial. The on-site facilitator-led interactive workshop aimed to help physicians review and integrate the concepts they acquired during the online training Patient components: decision support tools Materials: both the online tutorial and workshop included videos, exercises and decision aids to help physicians communicate to their patients the probability of a bacterial acute respiratory infection and the benefits and harms associated with the use of antibiotics Mode of delivery: online tutorial and facilitator-led interactive workshop Duration and intensity: 2-hour online tutorial followed by a 2-hour on-site interactive workshop Comparator: usual care

Outcomes	Primary: proportion of patients who decided to use antibiotics immediately after consultation (GP and patient self-administered questionnaire) Secondary: decisional conflict (GP/patient; Decisional Conflict Scale) Perception that shared decision making occurred (GP/patient; modified Control Preference Scale) Quality of decision made (GP/patient; single question Likert scale) Adherence to the decision (patient; single-item asking if decision made was maintained) Repeat consultation (for the same reason) (patient) Decisional Regret (patient; Decisional regret Scale) Quality of life (patient; SF-12) Intention to engage in SDM in future consultations regarding the use of antibiotics for ARIs (patients; questions based on Theory of Planned Behaviour) Intentions to engage in shared decision making (GP) Intention to adhere to clinical practice guidelines (GP) Preferred role in decision making (Control Preference Scale)	
Notes	Funding: yes Conflict of interest: none disclosed Published trial protocol: yes Trial registration: yes Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A biostatistician used Internet-based software to simultaneously randomise all 12 family practice teaching units to either the intervention group (DECISION+2) or control group. The teaching units were stratified according to rural or urban location
Allocation concealment (selection bias)	Unclear risk	The family practice teaching unites were recruited prior to randomisation, but it is not

		clear when the physicians in the units were recruited
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (due to the nature of the intervention and the self-administered outcomes)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Statistical analysis was performed by a statistician who was unaware of the teaching unit allocations
Incomplete outcome data (attrition bias) All outcomes	Low risk	12 family practice teaching units randomised; 9 participated in the study and all clusters completed the trial
Selective reporting (reporting bias)	Low risk	All indicated outcome reported. Prospective trial registration. Published trial protocol
Other bias	Unclear risk	Sample size calculation: yes ITT or per protocol analysis: not stated

Welschen 2004

Methods	Study design: cluster-randomised controlled trial Unit of randomisation: GP peer review group Trial duration: 2000 to 2002 Recruitment: general practitioners' (GP) peer review groups, with collaborating pharmacists (which aim to promote rational prescribing through audit and feedback), in the region of Utrecht, Netherlands, if the group consisted of ≥ 4 GPs and all agreed to participate Methods of data collection: during a 3-week period during 2000 and 2001 Data collection time points: index consultation Length of follow-up: nil
Participants	Primary care setting type: recruited from general practitioner (GP) peer review groups General practitioners: 100 GPs Patients: all registered patients presenting with acute symptoms of the respiratory tract *Relatively low prescription rates in the Netherlands

Interventions	Brief intervention name: multiple intervention Recipients: GPs and patients Providers: GP peer facilitators Health professional components: a) Group education meeting (jointly led a GP and pharmacist in each peer review group) included a review of previous years claims data, discussion of evidence-based medicine and communication of evidence for treatment benefit and risk to inform group consensus about the indication and first choice of antibiotics per indication (AOM, sinusitis, tonsillitis and acute cough); communication skills training (how to explore patients' worries and expectations and to inform patients about the natural course of the symptoms, self-medication and alarm symptoms). GPs received a summary of their group's guidelines by mail 1 week after the meeting, and received the results of the baseline measurement (to reinforce the consensus reached) after 2 months b) Monitoring and feedback on prescribing behaviour (6 months post-intervention) based on insurance claims data comparing the period after the intervention (March to May 2001) with the same period before the intervention (March to May 2000). Volumes of different kinds of antibiotics and the extent to which prescribed antibiotics were in line with the consensus about first choice antibiotics were presented at practice level c) Group education for assistants of GPs and pharmacists attended a 2-hour group education session informing them about Dutch guidelines for GPs, followed by skills training in educating patients Patient components: education material for patients consisted of a brochure and accompanying posters (also translated into Turkish and Arabic) available in waiting rooms of intervention group general practices, pharmacies and municipal health services, aiming to inform patients about the self-limiting character of most respiratory tract symptoms, self-medication and serious symptoms ("alarm signals") necessitating a consultation with the GP Materials: consensus guidelines for GPs and education material for patients Mode of delivery: GP and pharmacist-led group education meeting for GPs and assistants, and patient education brochure and posters

	Duration and intensity: 1 x group education meetings for GPs (duration not stated) and 1 x 2-hour group education meetings for assistants Comparator: usual care	
Outcomes	Primary: proportion of practice encounters for acute symptoms of the respiratory tract for which antibiotics were prescribed (patient records) Patient satisfaction (self-reported questionnaire; 1 = very dissatisfied to 5 = very satisfied) Secondary: administrative claims data (from regional health insurance company, Agis, over the period 2000 to 2002) (March to May, 2000 and March to May, 2001)	
Notes	Funding: yes Conflict of interest: none declared Published trial protocol: not reported Trial registration: not reported Ethics approval: yes	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The 12 peer review groups were allocated to groups A or B. All possible compositions of groups A and B were considered and the option chosen of those groups resulting in comparability between group A and B in groups with a high or low volume of antibiotic prescribing (above or below the median), rural or urban working groups, and number of general practitioners per group (above or below the median). MMK, who was blinded to the composition of the groups, flipped a coin to determine whether group A became the intervention or control group
Allocation concealment (selection bias)	Low risk	Not stated. However, practices recruited prior to randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (multiple intervention)
Blinding of outcome assessment (detection	Low risk	Research assistants blinded to the intervention status of the practices extracted

bias) All outcomes		information from patient records (age, sex, diagnoses, antibiotic prescriptions and referrals to hospital doctors) Patient satisfaction questionnaires returned directly to the investigators without being shown to the GP
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 42 of 48 peer-review groups in the Utrecht region that were invited to participate, 30 groups refused or were unable to participate. The 12 remaining peer-review groups were randomised to intervention (6 groups, 46 GPs) or control (6 groups, 54 GPs). All clusters and 89/100 GPs completed the study (intervention = 42, control = 49), with loss to follow-up due to retirement (n = 1), removal outside the region (n = 3), illness (n = 3), motivational problems (n = 2) or technical problems (n = 2)
Selective reporting (reporting bias)	Low risk	All indicative results reported
Other bias	Low risk	Sample size (power) calculation: yes ITT of per protocol analysis: yes

AOM: acute otitis media
ARI: acute respiratory infection
COPD: chronic obstructive pulmonary disease
CRP: C-reactive protein
FP: family physician
GP: general practitioner
ITT: intention-to-treat
LRTI: lower respiratory tract infection
n/a: not applicable
OTC: over-the-counter
RCT: randomised controlled trial
RTI: respiratory tract infection
SDM: shared decision making
URTI: upper respiratory tract infection

Table S2: Characteristics of excluded studies

Study	Reason for exclusion
Bourgeois 2010	Shared decision making not explicit or inferred
Gonzales 2013	Shared decision making not explicit or inferred
Pshetizky 2003	Shared decision making not explicit or inferred
Regev-Yochay 2011	Shared decision making not explicit or inferred
Samore 2005	Shared decision making not explicit or inferred
Taylor 2005	Shared decision making not explicit or inferred

Table S3: Characteristics of ongoing studies

Altiner 2012

Trial name or title	Converting habits of antibiotic prescribing for respiratory tract infections in German primary care - the cluster-randomised controlled (CHANGE-2) trial
Methods	3-arm cluster-randomised controlled trial
Participants	GPs (n = 94) or practice-based paediatricians (n = 94) and their patients (˜ 30,000 children and adults) who consult in general practices located in 2 German regions (Baden-Württemberg and Mecklenburg-Western Pomerania) for an ARI
Interventions	Communication training versus communication training and point of care testing (C-reactive protein and rapid antigen detection testing) versus control
Outcomes	Primary: physician antibiotic prescription rate for ARI at 2-year follow-up (post-intervention) derived from data of the statutory health insurance company Secondary: 1. Re-consultation rate 2. Use of medical services 3. Hospital admissions
Starting date	GP and paediatrician recruitment commenced October 2012; patient recruitment over 3 successive winter periods
Contact information	Prof Attila Altiner; Institute for General Practice, Rostock University Medical Center; POB 100888; Rostock 18055 Germany Phone: +49 (0)381 494 2481 Fax: +49 (0)381 494 2482 Email: ifa.sekretariat@med.uni-rostock.de
Notes	—

ARI: acute respiratory infection

Table S4: TIDieR [46] Intervention Summary

Item	Altiner 2007	Briel 2006	Butler 2012	Cals 2009	Francis 2009
	Complex GP peer-led educational intervention	Brief training programme in patient-centred communication	Multifaceted flexible blended learning approach for clinicians	Enhanced communication skills training	Interactive booklet for parents and clinician training in its use
Recipient	GPs and patients	GPs	GPs and nurse practitioners	GPs	GPs and patients
Why	Focused on communication within a consultation and the mutual discordance between patients' expectations and doctors' perceived patient expectations, empowering patients to raise the issue within the consultation. By 'informing' both sides in the consultation, it is hoped that doctors and patients would openly talk about the issue and thus reduce unnecessary antibiotic prescriptions	Focused on teaching GPs how to understand and modify patients' concepts and beliefs about the use of antibiotics for ARIs. GPs were introduced to a model (Prochaska 1992) for identifying patients' attitude and readiness for behaviour change	Blended learning experience to develop clinicians' sense of the importance about change and their confidence in their ability to achieve change based on Social Learning Theory Clinicians reflected on practice-level antibiotic dispensing and resistance data, reflected on own clinical practice (context-bound learning), and were trained in novel communication skills derived from principles of motivational interviewing	Focused on information exchange based on the elicit-provide-elicit framework from counselling in behaviour change - exploring patients' fears and expectations, patients' opinion on antibiotics and outlining the natural duration of cough in lower respiratory tract infections	Focused on specific communication skills, such as exploring parent's main concerns, asking about their expectations, and discussing prognosis, treatment options and reasons that should prompt re-consultation

Item	Altiner 2007	Briel 2006	Butler 2012	Cals 2009	Francis 2009
What (materials)	Peers used a semi-structured dialogue script for outreach visits Patient materials (leaflet and poster) provided in waiting room primarily focused on the patients' role doctor-patient 'antibiotic misunderstanding' and brief evidence-based information on acute cough and antibiotics	Evidence-based guidelines for diagnosis and treatment of ARIs (updated, locally adapted and reviewed by local experts) distributed as a booklet *[URL provided is no longer active]*	Summaries of research evidence and guidelines, web-based modules using video-rich material presenting novel communication skills, and a web-based forum to share experiences and views (see www.stemmingthetide.org for online component)	Pre- and post-workshop transcripts of simulated patients	8-page booklet (now at www.whenshouldIworry.com); online training in use of the booklet included videos to demonstrate use of the booklet within a consultation, as well as audio feeds, pictures and links to study materials *[URL no longer active]*
What (procedures)	GP peer-led outreach visits. Peers were trained to explore GPs' 'opposite' motivational background to address their beliefs and attitudes. GPs were motivated to explore patient expectations and demands, to elicit anxieties and make antibiotic prescribing a subject in the consultation	GPs were trained in elements of active listening, to respond to emotional cues, and to tailor information given to patients. Physicians used a model were introduced to a model (Prochaska	Intervention consist of 7 components: experiential learning, updated summaries of research evidence and guidelines; web-based learning in novel communication skills; practising consulting skills in routine care; facilitator-led practice-based seminar on practice-level data on antibiotic prescribing and resistance; reflections on own clinical practice, and a web-based	Brief context-learning based workshop in small groups (5 to 8 GPs), preceded and followed by practice-based consultations with simulated patients. GPs reflected on own transcripts of consultations with simulated patients, which	Booklet was given to parents to use in the consultation and as a take-home resource (no further details provided) Online training on the use of the booklet was provided to GPs: describing the content and aims of the booklet, and encouraging use within the consultation to facilitate use of specific communication skills

Item	Altiner 2007	Briel 2006	Butler 2012	Cals 2009	Francis 2009
	Patient materials were aimed at empowering patients to raise and clarify issues within the consultation	1992) to identify patients' attitude and readiness for behaviour change	forum to share experiences and views	were also peer-reviewed by colleagues	
Who provided	5 practising GPs and teaching academics in the lead authors' department (2 female, 33 to 63 years of age); trained in 3 sessions for outreach visits	Not specified	A facilitator conducted the face-to-face seminar	Experienced moderator to lead seminars	N/A (online training)
How	Face-to-face outreach visits to GPs	Seminar in small groups (number not specified) and personal feedback by telephone prior to the start of the trial. Evidence-based guidelines were distributed as a booklet	Intervention consisted of 7 parts (5 online modules, 1 face-to-face seminar and 1 facilitator-led practice-based seminar)	Brief workshop (5 to 8 GPs), preceded and followed by practice-based consultation with simulated patients	Parents used the booklet face-to-face in the consultation with GPs and took it home; GP training in use of booklet was online
Where	GP clinics during normal working hours	Not specified	The face-to-face and facilitator-led seminars were presented at the general practice	General practice	General practice; parents' homes

Item	Altiner 2007	Briel 2006	Butler 2012	Cals 2009	Francis 2009
When and how much	1 outreach visit performed per GP (duration not specified)	Attendance at 1 x 6-hour seminar and 1 x 2-hour telephone call to give personal feedback prior to the trial start	7 components (5 online, 1 face-to-face and 1 facilitator-led practice-based seminar) A booster module (6 to 8 months after completion of initial training) reinforced these skills	1 x 2-hour moderator-led small groups workshop, preceded and followed by practice-based consultation with simulated patients	1 x 40-minute online training module
Tailoring	Not described	Not described	The intervention was flexible so clinicians could access the online components and try out new skills with their patients at their convenience	Not described	Not described
Modification of intervention throughout trial	Not described	Not described	Not described	Not described	Not described
Strategies to improve or maintain intervention fidelity	Not described	Not described	Not described	Not described	Online clinician training monitored through study website: whether a GP has logged on to the site, how much time spent on it and which pages were viewed
Extent of intervention fidelity	51/52 GPs received the intervention	Not described	138/139 completed all online training and uploaded descriptions of consultations for the portfolio tasks; 129/139 attended the	66% of patients recruited by GPs allocated to training in enhanced communication skills	Stated that treatment fidelity was not measured so that assessors could remain blind to the study group

Item	Altiner 2007	Briel 2006	Butler 2012	Cals 2009	Francis 2009
			practice-based seminars; 76/139 completed the optional booster session at 6 months; 11/139 entered new threads on the online forum with 81 posts and 1485 viewings of posts and threads	recalled their GP's use at least 3 of 4 specific communication skills compared with 19% in the no training group	

ARI: acute respiratory infection; GP: general practitioner; N/A: not applicable

Table S4: (continued): TIDieR [46] Intervention Summary

Item	Légaré 2012	Légaré 2011	Little 2013	Welschen 2004
Brief name	Shared decision making training program (DECISION+2)	Multiple-component, continuing professional development program in shared decision making (DECISION+)	Internet-based training in enhanced communication skills	Group education meeting with consensus procedure and communication skills training
Recipient	Family physicians (including teachers and residents)	Family medicine groups (physicians and nurses)	GPs	GPs/pharmacists and their assistants, and patients
Why	A shared decision making training program that aimed to help physicians communicate to patients the probability of a bacterial ARI and the benefits and harms associated with the use of antibiotics	Aimed to help family physicians communicate to patients the probability of bacterial ARI and benefits and harms of antibiotic use	Rationale was that Internet-based training can be more widely disseminated than face-to-face training. Training focused on eliciting patients' expectations and concerns, natural disease course, treatments, agreement on a management plan, summing up and guidance on when to re-consult	GPs discussed evidence for antibiotic benefit/risk, and learned communication techniques to explore patients' expectations and concerns, inform about natural course of symptoms, self-medication and alarm symptoms. Patient education provided information on the self-limiting nature or ARIs, self-medication and alarm symptoms requiring re-consultation
What (materials)	Online tutorial and workshop included videos, exercises and decision aids to help physicians communicate to their patients the probability of bacterial ARIs and benefits/harms of antibiotic use.	Workshops included videos (simulated consultations of usual care and SDM) and exercises (facilitators and barriers to SDM). GPs trained in the use of 5 decision support tools using video	Interactive booklet for use by GPs within consultations Training supported by video demonstrations of consultation techniques	Group consensus guidelines and patient waiting room materials (poster/leaflets)

Item	Légaré 2012	Légaré 2011	Little 2013	Welschen 2004
	Decision aids were available in the consultation rooms in all family practice teaching units	examples and group exercises. A booklet summarising workshop content provided to participants. Postcard reminders sent		
What (procedures)	Online self-tutorial comprising 5 modules 2-hour online tutorial followed by a facilitator-led on-site interactive workshops aimed to help physicians review and integrate concepts acquired during online training	Interactive workshops and related material, reminders of expected behaviours and GP feedback on agreement between their decisional conflict and that of their patients	Online modules and an interactive booklet for use within consultations. (Group practices also appointed a lead GP to organise a structured meeting on prescribing issues)	Group education meeting with consensus procedure, with a summary, and guidelines mailed 1 month later to reinforce consensus reached; feedback on prescribing behaviour (post- and pre-intervention insurance claims data) and practice-level reporting of extent prescribing behaviours aligned with consensus reached; group education session for GP and pharmacists assistants (Dutch guidelines and skills training in patient education); waiting room education al material for patients
Who provided	Trained facilitators	Trained facilitators	N/A (online modules) other than lead GP at each practice to organise a meeting (not specific to just this arm of the intervention though)	Jointly led by GP and pharmacist
How	Online tutorial and face-to-face workshop	Face-to-face workshop	Online modules (and GP-led structured practice-based meeting)	Group education meeting for GPs with consensus procedure and communication skills training,

Item	Légaré 2012	Légaré 2011	Little 2013	Welschen 2004
				Group education for GPs' and pharmacists' assistants, monitoring and feedback on prescribing behaviour, and patient education materials
Where	Family practice teaching units	Family medicine groups	General practice	Not described
When and how much	1 x 2-hour online tutorial followed by 1 x 2-hour on-site interactive workshop Participants had 1 month to complete the programme	3 x 3-hour interactive workshops and related material, in addition to reminders of expected behaviours and GP feedback on agreement between their decisional conflict and that of their patients. DECISION+ conducted over 4 to 6 months	Internet modules completed alone or in a group	1 x group education meeting with consensus procedure; 1 x 2-hour group education session for GP and pharmacists' assistants; monitoring and feedback of prescribing behaviour at 6 months post-intervention
Tailoring	Not described	Not described	Not described	Not described
Modification of intervention throughout trial	Not described	4 pilot workshops held rather than 3 as the second workshop was redesigned and re-piloted after feedback on its first testing	Not described	Not described
Strategies to improve or maintain intervention fidelity	Not described	Not described	Not described	Not described

Item	Légaré 2012	Légaré 2011	Little 2013	Welschen 2004
Extent of intervention fidelity	Of the 162 physicians, 103 completed both the online tutorial and workshop; 16 completed only the workshop; 15 only the tutorial; and 28 completed none of the training components	Not described	94/108 practices (87%) completed the communication training. Mean (SD) time spent on the website was 37 (29) minutes	Not described

ARI: acute respiratory infection; GP: general practitioner; N/A: not applicable; SDM: shared decision making

Table S5: Antibiotic prescriptions per index consultation or population rate over time

Author	Outcome	Measurement time point	Intervention (n)	Control	Effect estimate	P value	Notes
					Adjusted odds ratio (95% CI)		
Francis (2009)	Antibiotics prescribed at the index consultation	14 days	(30 practices) Patients = 50/256 (19.5%)	(31 practices) Patients = 111/272 (40.8%)	0.29 (0.14 to 0.60)[a]	NR	ICC = 0.24
Altiner (2007)	Rate of antibiotic prescriptions (per acute cough and per GP)	6 weeks	GPs = 42 Patients = 1021	GPs = 44 Patients = 1143	0.38 (0.26 to 0.56)[b]	< 0.001	ICC = 0.20
		12 months	GPs = 28 Patients = 787	GPs = 33 Patients = 920	0.55 (0.38 to 0.80)[b]	0.002	
Briel (2006)	Uptake of antibiotic prescriptions as reported by pharmacists < 2 weeks after the consultation	14 days	GPs = 15 Patients = 259	GPs = 15 Patients = 293	0.86 (0.40 to 1.93)[c]	NR	ICC = 0.04 Design effect = 1.6
					Adjusted risk ratio (95% CI)		
Little (2013)	Antibiotic prescription	index consultation	Practices = 61 Patients = 2332	Practices = 61 Patients = 1932	0.69 (0.54 to 0.87)[d]	< 0.0001	—
Légaré (2012)	% patients who decided to use antibiotics	Index consultation	Practice units = 6 GPs = 77 Patients = 181	Practice units = 6 GPs = 72 Patients = 178	0.50 (0.30 to 0.70)[e]	—	—

Author	Outcome	Measurement time point	Intervention (n)	Control	Effect estimate	P value	Notes
	immediately after the consultation						
					Adjusted risk difference (95% CI)		
Légaré (2011)	% patients who decided to use antibiotics immediately after the consultation	Index consultation	Medicine groups = 2 GPs = 18 Patients = 81	Medicine groups GPs = 14 Patients = 70	-16 (-31 to 1)[f]	0.08	—
Butler (2012)	Total no. dispensed oral antibiotic items per 1000 registered patients for the year after the intervention	12-month period	Practices = 34 Patients = 7053	Practices = 34 Patients = 7050	-4.2 (-0.6 to -7.7)	0.02	—
Cals (2009)	Antibiotic prescribing at the index consultation	Index consultation	n/N = 55/201 % crude (95% CI)[G] 27.4 (25.6 to 36.6)	n/N = 123/230 % crude (95% CI)[g] 53.5 (43.8 to 63.2)	-26.1 (% crude)	< 0.01[h]	ICC = 0.12
Cals (2013)	Proportion of episodes of respiratory tract infections during follow-up for which a GP was seen and that antibiotics were prescribed for	Mean 3.67 years follow-up	n = 178 % (95% CI) 26.3 (20.6 to 32.0)	n = 201 % (95% CI) 39.1 (33.1 to 45.1)	-10.4[i]	0.02[i]	—
Welschen (2006)	% practice encounters for acute symptoms of the	Index consultation	Review groups = 6	Review groups = 6	–10.7 (–20.3 to –1.0)[j]	—	Practice = 0.17 Review group = 0.09

Author	Outcome	Measurement time point	Intervention (n)	Control	Effect estimate	P value	Notes
	respiratory tract for which antibiotics were prescribed						

[a]Two level (practice and patient) random intercept logistic regression models.

[b]After backward elimination, four explanatory variables remained in the model: patients' disease severity, measured on a four-point scale (odds ratio 4.8, 95% CI 3.9 to 5.9 per step on scale, P value < 0.001), and average practice severity (severity of the disease rated by the GP) (odds ratio 0.14, 95% CI 0.06 to 0.33, P value < 0.001 per category step on the scale), patients having fever (odds ratio 1.80, 95% CI 1.35 to 2.39, P value < 0.001 compared with no fever) and frequency of fever in practice, as determined by the log odds (odds ratio 1.31, 95% CI 1.08 to 1.59, P value = 0.007 per category step on the scale).

[c]Logistic regression with random effects for each cluster and patient covariates (age, sex, education, days with restrictions at baseline).

[d]The adjusted model adjusted for baseline prescribing and clustering by physician and practice, and additionally controlled for age, smoking, sex, major cardiovascular or respiratory comorbidity, baseline symptoms, crepitations, wheeze, pulse higher than 100 beats per minute, temperature higher than 37.8°C, respiratory rate, blood pressure, physician's rating of severity and duration of cough.

[e]Adjusted for cluster design, baseline values and patient age group (for analyses at teaching unit and physician levels).

[f]P value adjusted for baseline values and the study's cluster design.

[g]Calculated and inflated for clustering by using standard deviation inflated by variance inflation factor.

[h]Calculated from second order penalised quasi-likelihood multilevel logistic regression model adjusted for variance at general practitioner and practice level (random intercept at practice and general practitioner level). Models included both interventions and interaction term of interventions.

[i]P values from multilevel linear regression model to account and correct for variation at the level of family physician, and to adjust for both interventions, RTI-episodes treated with antibiotics during baseline period, chronic obstructive pulmonary disease comorbidity.

[j]Intervention effect in multi-level analysis

CI: confidence interval; GP: general practitioner; NR: not reported

Table S6: Number or rate of re-consultations

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Briel (2006)	Re-consultation	Within 14 days	n/N (%) 113/253 (44.7)	n/N (%) 143/290 (49.3)	Adjusted rate ratio (95% CI)[a] 0.97 (0.78 to 1.21)	NR	—
Butler (2013)	Re-consultation after index consultation)[b]	Within 7 days Within 14 days Within 31 days	Median (IQR) 2.66 (1.88 to 4.25) 5.10 (4.70 to 7.92) 9.06 (7.53 to 12.62)	Median (IQR) 3.35 (2.16 to 4.31) 6.43 (4.04 to 7.84) 11.38 (7.39 to 14.05)	Median difference (95% CI)[c] -0.65 (-1.69 to 0.55) -1.33 (-2.12 to 0.74) -2.32 (-4.76 to 1.95)	 P value = 0.446[d] P value = 0.411[d] P value = 0.503[d]	—
Cals (2009)	Re-consultation	Within 28 days	n/N = 56/201 % crude (95% CI)[e] 27.9 (21.4 to 34.4)	n/N = 85/230 % crude (95% CI)[e] 37.0 (30.4, 43.6)	 Absolute difference 9.1 (% crude)	0.14[f]	ICC = 0.01
Francis (2009)	Re-consultation[g]	Within 14 days	n/N (%) 33/256 (12.9)	n/N (%) 44/272 (16.2)	Adjusted odds ratio (95% CI) 0.75 (0.41 to 1.38)	NR	ICC = 0.06
Légaré (2012)	Re-consultation	Baseline (pre)	21.6 (12.1 to 29.7)	22.7 (10.3 to 27.3)	Adjusted risk ratio (95% CI)[h] 1.3 (0.7 to 2.3) Absolute difference = 7.5	NR	—
		Within 14 days (post)	13.4 (9.9 to 15.9)	15.2 (11.9 to 19.4)			
Little (2013)	New or worsening symptoms[i]	—	n/N (%) 451/2242 (20%)	n/N (%) 309/1879 (16%)	Adjusted risk ratio (95% CI)[j] 1.33 (0.99 to 1.74)	P value = 0.055	—

[a]Poisson regression with random effects for each cluster and patient covariates (age, sex, education, days with restrictions at baseline).

[b]Collected from the electronic records of a subsample of 37 general practices (20 intervention/17 control). 47 patients (10.9%) re-consulted more than once

within 28 days with pattern similar across groups.

[c]Computed with bootstrapping methods.

[d]From Mann-Whitney U test.

[e]Calculated and inflated for clustering by using standard deviation inflated by variance inflation factor.

[f]Calculated from second order penalised quasi-likelihood multilevel logistic regression model adjusted for variance at general practitioner and practice level (random intercept at practice and general practitioner level). Models included both interventions and interaction term of interventions.

[g]Parental report that child attended a face-to-face consultation with a primary care clinician in their general practice, or with an out of hours provider, in the 2 weeks after registration.

[h]Adjusted for cluster design and baseline values.

[i]Defined as re-consultation for new or worsening symptoms within 4 weeks, new signs or hospital admission.

[j]The adjusted model adjusted for baseline prescribing and clustering by physician and practice, and additionally controlled for age, smoking, sex, major cardiovascular or respiratory comorbidity, baseline symptoms, crepitations, wheeze, pulse higher than 100 beats per minute, temperature higher than 37.8°C, respiratory rate, blood pressure, physician's rating of severity and duration of cough.

CI: confidence interval; ICC: intra-class correlation co-efficient; IQR: interquartile range; NR: not reported

Table S7: Incidence of hospital admissions

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Briel (2006)	Hospital admissions	< 28 days of study enrolment	n/N = 2/253	n/N = 1/290	NR	NR	—
Butler (2012)	Hospital admissions[a]	Baseline Follow-up	Mean 7.7 7.5	Mean 8.7 8.0	% reduction (intervention relative to controls[b] (95% CI) -1.9 (-13.2 to 8.2)	P value = 0.72	—
Cals (2013)	Hospital admissions	Mean 3.67 year follow-up	n/N 0/178	n/N 5/201	NR	NR	—
Francis (2009)	Hospital admissions (or observed in a paediatric assessment unit)	< 14 days	n/N 3/256	n/N 4/272	NR	NR	—
Little (2013)	Hospital admissions[c]	< 4 weeks	n/N 6/1170	n/N 2/870	NR	—	—

[a]Annual number of hospital episodes for possible respiratory tract infections and complications of common infections per 1000 registered patients. A single admission occurred if patient admitted to hospital for a possible RTI or complication. If patient admitted more than once, and gap between admissions was 30 days or more, this was considered a separate complication episode.

[b]Difference between means in intervention group and control group as percentage of mean control group.

[c]Factorial analysis data not reported

NR: not reported; RTI: respiratory tract infection; SAEs: serious adverse events

Table S8: Incidence of pneumonia

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Briel (2006)	Pneumonia	< 28 days	n/N = 0/253	1/290	NR	NR	—
Cals (2013)	Pneumonia	Mean 3.67 year follow-up	n/N = 0/178	n/N = 1/201	NR	NR	—

NR: not reported

Table S9: Patient satisfaction

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Briel (2006)	Patient satisfaction (Patient Satisfaction Questionnaire)[a]	7 and 14 days	121/253 (47.8)	142/290 (49.0)	Adjusted OR (95% CI)[b] 1.00 (0.64 to 1.31)	NR	—
Cals (2009)	Patient satisfaction (% at least 'very satisfied' on Likert scale)[c]	28 days	n/N = 144/201 % (crude 95% CI)[d] 78.7 (72.5 to 84.9)	n/N = 151/230 % (crude 95% CI)[d] 74.4 (68.2 to 80.6)	4.3	P value = 0.88[e]	—
Francis (2009)	Parent satisfaction (Likert scale)[f]	14 days	n/N (%) = 222/246 (90.2)	n/N (%) = 246/263 (93.5)	Adjusted OR (95% CI)[g] 0.6 (0.3 to 1.2)	NR	—
Welschen (2006)	Patient satisfaction (Likert scale)[h]	Index consultation	Patient satisfaction (%) Baseline (pre) = 4.3 (0.3) Follow-up (post) = 4.3 (0.3) % change (SD) = 0 (0.4)	Patient satisfaction (%) Baseline (pre) = 4.2 (0.4) Follow-up (post) = 4.2 (0.3) % change (SD): 0 (0.4)	Mean difference of changes (95% CI) 0 (–0.2 to 0.1) [i]	NR	—

[a]% patients with a maximum score of 70 reported, as satisfaction scores (scale 14 to 70; median 68/70) were highly skewed.

[b]Logistic regression with random effects for each cluster and patient covariates (age, sex, education, days with restrictions at baseline).

[c]% at least 'very satisfied'.

[d]Calculated and inflated for clustering by using standard deviation inflated by variance inflation factor.

[e]Calculated from models adjusted for variance at general practitioner and practice level.

[f]Transformed into binary outcomes: 'very satisfied' and 'satisfied' versus 'neutral', 'dissatisfied' and 'very dissatisfied'.

[g]Odds ratio (95% CI) from multilevel modelling.

[h]1 = very dissatisfied to 5 = very satisfied.

[i]Intervention effect in multilevel analysis.

CI: confidence interval; OR: odds ratio; SD: standard deviation

Table S10: Decisional conflict

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Légaré (2012)	Decisional conflict (GPs)[a]	Immediately after consultation	Baseline: 4.5 (0 to 9.0) Follow-up: 4.6 (0 to 6.1)	Baseline: 3.0 (0 to 5.9) Follow-up:1.1 (0 to 2.4)	Adjusted RR 3.4 (0.3 to 38.0)	NR	—
Légaré (2012)	Decisional conflict (patients)[a]	Immediately after consultation	Baseline: 5.1 (0 to 13.5) Follow-up: 4.6 (2.6 to 7.4)	Baseline: 4.2 (0 to 8.9) Follow-up: 6.3 (0 to 12.8)	Adjusted RR: 0.8 (0.2 to 2.4)	NR	—
Légaré (2011)	Correlation of decisional conflict between GPs and patients[a]	Immediately after consultation	Baseline: 0.14 Follow-up: 0.24	Baseline: -0.05 Follow-up: 0.02	Difference at follow-up (95% CI) 0.26 (-0.06 to 0.53)	0.06	—

[a]Proportion of participants who had a value of 2.5 or more on the Decision Conflict Scale (where 1 = low decisional conflict and 5 = very high decisional conflict).

[b]Presented as correlation of family physicians' and patient's DCS scores (Pearson's r).

CI: confidence interval; GP: general practitioner; NR: not reported; RR: risk ratio

Table S11: Decisional regret

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Légaré (2012)	Decisional regret[a]	2 weeks after consultation	Baseline: 10.5 ± 15.4 Follow-up: 12.4 ± 19.1	Baseline: 10.8 ± 20.8 Follow-up: 7.6 ± 13.7	Adjusted mean difference 4.8 (0.9 to 8.7)	—	—
Légaré (2011)	Patients (%) with decisional regret	2 weeks after consultation	Baseline: 1 Follow-up: 7	Baseline: 1 Follow-up: 9	Difference at follow-up (95% CI) -2 (-12 to 5)	0.91	—

a = Decisional Regret Scale used, where 0 = very low regret and 100 = very high regret

CI: confidence interval

Table 12: Patient enablement

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Briel (2006)	Patient enablement (Patient Enablement Instrument; scale 0 to 12)	7 and 14 days	Mean (SD): 8.49 (1.98)	Mean (SD): 8.15 (2.03)	Adjusted coefficient (95% CI)[a] 0.35 (-0.05 to 0.75)	NR	—
Cals (2009)	Patient enablement (Patient Enablement Instrument; max. score is 12)	28 days	Median (IQR) score: 3 (4) Mean (SD) score: 3.29 (2.52)	Median (IQR) score: 3 (4)[d] Mean (SD) score: 3.06 (2.54)	—	NR 0.70[b]	—
Francis (2009)	Parent enablement (Modified Patient Enablement Instrument, scale 1 to 10)[c]	14 days	n/N (%): 99/246 (40.2)	n/N (%): 94/262 (35.9)	Adjusted OR (95% CI) 1.20 (0.84 to 1.73)	NR	—

[a]Linear regression with random effects for each cluster and patient covariates (age, sex, education, days with restrictions at baseline).

[b]Calculated from models adjusted for variance at general practitioner and practice level.

[c]Presented results are % with parent enablement score of 5 or more (binary outcome).

[d]Comparator is 'no skills training'.

CI: confidence interval; IQR: interquartile range; NR: not reported; OR: odds ratio; SD: standard deviation

Table S13: Quality of the decision made (GPs)

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Légaré (2012)	Quality of decision made (GPs) (0 to 10 Likert scale)	After consultation	Baseline: 8.7 ± 1.5 Follow-up: 8.5 ± 1.6	Baseline: 8.7 ± 1.5 Follow-up: 8.5 ± 1.5	Adjusted mean difference 0.0 (-0.4 to 0.4)	NR	—
Légaré (2011)	Quality of decision made (GPs) (0 to 10 Likert scale)	After consultation	Baseline: 8.8 ± 1.1 Follow-up: 8.7 ± 1.2	Baseline: 8.3 ± 1.4 Follow-up: 8.5 ± 1.3	Difference at follow-up (95% CI) 0.2 (-0.34 to 0.89)	0.29	—

CI: confidence interval; GP: general practitioner; NR: not reported

Table S14: Quality of the decision made (Patients)

Author	Outcome	Measurement time point	Intervention	Control	Effect estimate	P value	Notes
Légaré (2012)	Quality of decision made (patients) (0 to 10 Likert scale) [a]	After consultation	Baseline: 8.2 ± 1.1 Follow-up: 8.2 ± 1.3	Baseline: 8.2 ± 1.4 Follow-up: 8.4 ± 1.0	Adjusted mean difference 0.2 (-0.6 to 0.2)	NR	—
Légaré (2011)	Quality of the decision made (patients) (0 to 10 Likert scale) [a]	After consultation	Baseline: 8.2 ± 2.1 Follow-up: 8.7 ± 1.9	Baseline: 8.4 ± 1.9 Follow-up: 8.6 ± 1.9	Difference at follow-up (95% CI) 0.1 (-0.88 to 0.94)	0.57	—

[a]Likert scale where 0 = very low quality and 10 = very high quality.

CI: confidence interval; NR: not reported

Table S15: Electronic search strategy

MEDLINE (Ovid) search strategy

1	exp Respiratory Tract Infections/ (297579)
2	(respiratory adj2 (infection* or inflam*)).tw. (31350)
3	pharyngitis.tw. (4164)
4	sinusit*.tw. (11403)
5	(acute adj2 rhinit*).tw. (174)
6	(rhinosinusit* or nasosinusit*).tw. (4197)
7	common cold*.tw. (2806)
8	coryza.tw. (379)
9	(throat* adj2 (sore* or inflam* or infect*)).tw. (3897)
10	laryngit*.tw. (1305)
11	tonsillit*.tw. (4080)
12	bronchit*.tw. (18478)
13	bronchiolit*.tw. (8053)
14	pneumon*.tw. (133425)
15	(bronchopneumon* or pleuropneumon*).tw. (5382)
16	Cough/ (12409)
17	cough*.tw. (34227)
18	exp Otitis Media/ (21649)
19	otitis media.tw. (16032)
20	(aom or ome).tw. (6083)
21	Croup/ (970)
22	(croup or pseudocroup or laryngotracheobronchit* or laryngotracheit*).tw. (1971)
23	or/1-22 (451019)
24	exp Anti-Bacterial Agents/ (537825)
25	antibiotic*.tw,nm. (242634)
26	or/24-25 (640170)
27	23 and 26 (79549)
28	exp Decision Making/ (122846)
29	exp decision support techniques/ (62827)

30 exp Decision Theory/ (9884)

31 (decision* or decid* or option* or choice* or choose* or deliberat*).tw. (618268)

32 exp Informed Consent/ (35917)

33 (informed adj3 (consent* or agree* or assent*)).tw. (23002)

34 Health Knowledge, Attitudes, Practice/ (74387)

35 "Attitude of Health Personnel"/ (92103)

36 professional-patient relations/ or physician-patient relations/ (82522)

37 exp Consumer Participation/ (32440)

38 ((patient* or consumer* or carer* or parent* or child* or individual* or person* or interpersonal*) adj5 (participat* or involv* or collabor* or cooperat* or co-operat* or engag* or consult* or feedback* or interaction*)).tw. (184609)

39 (values* or prefer*).tw. (981018)

40 exp Communication/ (369188)

41 (communicat* or negotiat* or facilitat* or discuss*).tw. (1366627)

42 health education/ or exp consumer health information/ or patient education as topic/ (125443)

43 ((patient* or consumer* or parent*) adj3 (educat* or informat*)).tw. (58615)

44 (shar* adj2 information*).tw. (3292)

45 sdm.tw. (869)

46 ((patient* or client* or subject or person or consumer* or family or families or carer* or care giver*) and (professional* or physician* or clinician* or practitioner*)).tw. (327702)

47 Risk Assessment/ (180413)

48 ((check or clarify) adj3 understanding).tw. (222)

49 (patient adj2 (understanding or expect*)).tw. (3479)

50 problem defin*.tw. (230)

51 (ask adj2 question*).tw. (1819)

52 (assess* adj2 risk*).tw. (50234)

53 self-manag*.tw. (8193)

54 equipoise.tw. (596)

55 checklist*.tw. (18085)

56 (goal adj2 set*).tw. (2180)

57 consensus.tw. (98026)

58 concordance.tw. (26142)

59 agreement*.tw. (155845)

60 (action* adj2 plan*).tw. (5452)

61 or/28-60 (3975067)

62 27 and 61 (14717)

Table S15 (continued): Electronic search strategy

EMBASE (Elsevier) search strategy

#53 #23 AND #26 AND #52 28861

#52 #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 3678076

#51 'self-manage':ab,ti OR equipoise:ab,ti OR checklist:ab,ti OR consensus:ab,ti OR concordance:ab,ti OR agreement*:ab,ti OR (action* NEAR/2 plan*):ab,ti OR (goal NEAR/2 set*):ab,ti AND [embase]/lim298331

#50 (assess* NEAR/2 risk*):ab,ti AND [embase]/lim53641

#49 (ask NEAR/2 question*):ab,ti AND [embase]/lim1736

#48 (problem NEAR/1 defin*):ab,ti AND [embase]/lim327

#47 (patient NEAR/2 (understanding OR expect*)):ab,ti AND [embase]/lim4348

#46 ((check OR clarify) NEAR/3 understanding):ab,ti AND [embase]/lim203

#45 'risk assessment'/de AND [embase]/lim276013

#44 patient*:ab,ti OR client*:ab,ti OR subject:ab,ti OR person:ab,ti OR consumer*:ab,ti OR family:ab,ti OR families:ab,ti OR carer*:ab,ti OR 'care giver':ab,ti OR 'care givers':ab,ti AND (professional*:ab,ti OR physician*:ab,ti OR clinician*:ab,ti OR practitioner*:ab,ti) AND [embase]/lim349162

#43 sdm:ab,ti AND [embase]/lim776

#42 (shar* NEAR/2 information*):ab,ti AND [embase]/lim2631

#41 ((patient* OR consumer* OR parent*) NEAR/3 (educat* OR informat*)):ab,ti AND [embase]/lim59024

#40 'patient education'/de OR 'consumer health information'/de AND [embase]/lim41224

#39 communicat*:ab,ti OR negotiat*:ab,ti OR facilitat*:ab,ti OR discuss*:ab,ti AND [embase]/lim1335786

#38 'interpersonal communication'/de OR 'communication skill'/de OR 'nonverbal communication'/exp OR 'persuasive communication'/de OR 'verbal communication'/de OR 'conversation'/de AND [embase]/lim117435

#37 values*:ab,ti OR prefer*:ab,ti AND [embase]/lim995711

#36 ((patient* OR consumer* OR carer* OR parent* OR child* OR individual* OR person* OR interpersonal*) NEAR/5 (participat* OR involv* OR deliberat* OR collabor* OR cooperat* OR 'co-operate' OR 'co-operates' OR 'co-operation' OR engag* OR consult* OR feedback* OR interaction*)):ab,ti AND [embase]/lim197067

#35 'patient participation'/de AND [embase]/lim6904

#34 'doctor patient relation'/de AND [embase]/lim39102

#33 'attitude to health'/de AND [embase]/lim7634

#32 (treatment* NEAR/2 option*):ab,ti AND [embase]/lim65145

#31 (informed NEAR/3 (consent* OR agree*)):ab,ti AND [embase]/lim32077

#30 'informed consent'/de AND [embase]/lim39300

#29 decision*:ab,ti OR decid*:ab,ti OR option*:ab,ti OR choice*:ab,ti OR choose*:ab,ti OR deliberat*:ab,ti AND [embase]/lim639112

#28 'decision support system'/de AND [embase]/lim4763

#27 'decision making'/de OR 'patient decision making'/de OR 'medical decision making'/de OR 'clinical decision making'/de AND [embase]/lim158809

#26 #24 OR #25 892667

#25 antibiotic*:ab,ti AND [embase]/lim219681

#24 'antibiotic agent'/exp AND [embase]/lim842466

#23 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 518323

#22 croup:ab,ti OR pseudocroup:ab,ti OR laryngotracheobronchit*:ab,ti OR laryngotracheit*:ab,ti AND [embase]/lim1492

#21 'otitis media':ab,ti OR aom:ab,ti OR ome:ab,ti AND [embase]/lim19731

#20 'otitis media'/exp AND [embase]/lim21150

#19 cough*:ab,ti AND [embase]/lim37668

#18 'coughing'/de AND [embase]/lim52337

#17 bronchopneumon*:ab,ti OR pleuropneumon*:ab,ti AND [embase]/lim3817

#16 pneumon*:ab,ti AND [embase]/lim131768

#15 bronchiolit*:ab,ti AND [embase]/lim8788

#14 bronchit*:ab,ti AND [embase]/lim15885

#13 tonsillit*:ab,ti AND [embase]/lim3497

#12 laryngit*:ab,ti AND [embase]/lim1237

#11 (throat* NEAR/2 (sore* OR inflam* OR infect*)):ab,ti AND [embase]/lim4582

#10 'sore throat'/de AND [embase]/lim8854

#9 'common cold':ab,ti OR 'common colds':ab,ti OR coryza:ab,ti AND [embase]/lim2828

#8 'common cold symptom'/de AND [embase]/lim269

#7 rhinosinusit*:ab,ti OR nasosinusit*:ab,ti AND [embase]/lim4585

#6 (acute NEAR/2 rhinit*):ab,ti AND [embase]/lim179

#5 sinusit*:ab,ti AND [embase]/lim11343

#4 pharyngit*:ab,ti AND [embase]/lim4248

#3 (respiratory NEAR/2 (infection* OR inflam*)):ab,ti AND [embase]/lim33268

#2 'respiratory tract inflammation'/exp AND [embase]/lim275986

#1 'respiratory tract infection'/exp AND [embase]/lim198937

Table S15 (continued): Electronic search strategy

Web of Science (Thomson Reuters) search strategy

#7 #6 AND #5

DocType = All document types; Language = All languages;

#6 **TOPIC:** *(random* or placebo* or ((singl* or doubl*) NEAR/1 blind*) or allocat* or crossover* or "cross over") OR* **TITLE:** *(trial)*

DocType=All document types; Language=All languages;

#5 #4 AND #3

DocType=All document types; Language=All languages;

#4 **TOPIC:** *(sdm or decision* or decid* or choice* or prefer* or option*) OR* **TOPIC:** *((informed NEAR/3 (consent* or agree*))) OR***TOPIC:** *((patient* or consumer* or parent* or personal* or individual* or interpersonal*) NEAR/2 (participat* or involv*))*

DocType=All document types; Language=All languages;

#3 #2 AND #1

DocType=All document types; Language=All languages;

#2 **TOPIC:** *(antibiotic* or antibacterial* or anti-bacterial*)*

DocType=All document types; Language=All languages;

#1 **TOPIC:** *(pharyngit* or sinusit* or "acute rhinitis" or rhinosinusit* or nasosinusit* or "common cold*" or coryza or laryngit* or tonsillit* or bronchit* or bronchiolit* or pneumon* or bronchopneumon* or pleuropneumon* or cough* or "otitis media" or aom or ome or croup or pseudocroup or laryngotracheit* or laryngotracheobronchit*) OR* **TOPIC:** *((respiratory NEAR/2 (infect* or inflam*)) or (throat* NEAR/2 (sore* or inflam* or infect*)))*

DocType=All document types; Language=All languages;

Chapter 5

Parents' Expectations and Experiences of Antibiotics for Acute Respiratory Infections in Primary Care

Peter Coxeter, Chris Del Mar, Tammy Hoffmann

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Altmetric score: 60 (as of August 2017; top 8% of all articles published by this journal)

Preamble to Chapter 5

Previous work by others has reported modifiable clinician-and patient-related factors that strongly influence antibiotic prescribing for adults and children with ARIs in primary care.[1,2] Non-clinical reasons such misunderstandings or inaccurate treatment expectations appear important to primary care prescribing of antibiotics for adults and children with an ARI. Clinicians may just want to do something to help, feel pressured to prescribe due to perceived expectation for an antibiotic, and an attempt to uphold patient satisfaction. Patients (or parents) may also explicitly demand an antibiotic. A recent systematic review found inaccurate perceptions of treatment benefits and harm may be key driver of patient demands for unnecessary treatments and tests.[3] This may also help to explain patient demand for antibiotics for ARIs in primary care.

This study focussed on use of antibiotics for ARIs in children, because this population more commonly experience ARIs and receive an antibiotic. Findings from the systematic review presented in Chapter 4 was that few studies included children. This chapter describes Study 2 and consists of the paper titled *"Parents' Expectations and Experiences of Antibiotics for Acute Respiratory Infections in Primary Care"*, published in Annals of Family Medicine in March 2017. It explores parents' beliefs about antibiotic necessity for common ARIs in children, quantifies their expectations of antibiotic benefit, and reports on their experiences managing childhood ARIs with other prescription, over-the-counter, and complementary and alternative medicines, and exposure to and preferences for shared decision making.

Work arising from this study was also presented at the joint International Society for Evidence Based Health Care and International Shared Decision-Making Conference 2015, and the Gold Coast Health and Medical Research Conference 2014. Preliminary findings were also accepted for a presentation at the Primary Health Care Research Conference (PHCRIS), 2014.

Abstract

Purpose

Primary care visits for children with acute respiratory infections frequently result in antibiotic prescriptions, although antibiotics have limited benefits for common acute respiratory infections and can cause harms, including antibiotic resistance. Parental demands are often blamed for antibiotic prescription. We aimed to explore parents' beliefs about antibiotic necessity, quantify their expectations of antibiotic benefit, and report experiences of other management options and exposure to and preferences for shared decision making.

Methods

We conducted computer-assisted telephone interviews in an Australia-wide community sample of primary caregivers, hereafter referred to as parents, of children aged 1 to 12 years, using random digit dialling of household landline telephones.

Results

Of the 14,505 telephone numbers called, 10,340 were eligible numbers; 589 potentially eligible parents were reached, of whom 401 were interviewed. Most believed antibiotics provide benefits for common acute respiratory infections, especially for acute otitis media (92%), although not using them, particularly for acute cough and sore throat, was sometimes acceptable. Parents grossly overestimated the mean benefit of antibiotics on illness symptom duration by 5 to 10 times, and believed they reduce the likelihood of complications. The majority, 78%, recognized antibiotics may cause harm. Recalling the most recent relevant doctor visit, 44% of parents reported at least some discussion about why antibiotics might be used; shared decision making about antibiotic use was inconsistent, while 75% wanted more involvement in future decisions.

Conclusions

Some parents have misperceptions about antibiotic use for acute respiratory infections, highlighting the need for improved communication during visits, including shared decision making to address overoptimistic expectations of antibiotics. Such communication should be one of several strategies that is used to reduce antibiotic use.

Introduction

Children experience 4 to 12 acute respiratory infections annually,[4] and primary care clinicians too often prescribe antibiotics [5-7] despite strong evidence that they typically provide only marginal benefits.[8-11] Common harms and the contribution to antibiotic resistance,[12] now a global public health crisis,[13,14] are rarely addressed. Primary care clinicians resort to antibiotics for many reasons, including diagnostic uncertainty;[1,15] a desire to provide an unwell child with something to help;[1,16] and an attempt to reduce visit length [1,15] and achieve parental satisfaction.[17] Interacting with many of these reasons is parental pressure for antibiotics, both articulated and perceived by clinicians.[1] It is known that patients overestimate benefits and underestimate harms for many medical treatments.[3] We conducted a systematic review that found no studies specifically assessing these measures for acute respiratory infections,[3] so we aimed to explore parents' beliefs about antibiotic necessity, quantify their expectations of antibiotic benefit, and report the experiences of other management options and exposure to and preferences for shared decision making.

Methods

We developed a questionnaire, pilot testing it to establish face validity and refine question format and sequence. We used convenience samples of 9 eligible parents interviewed face to face and 12 subsequently interviewed by telephone. Our Australia-wide survey of parents of at least 1 child aged 1 to 12 years used computer-assisted telephone interviewing (CATI) by an independent research organization. Randomly selected household landlines were telephoned between May and July 2014, and the child's or children's eligible primary caregiver, hereafter referred to as parent, was asked a series of questions (Supplemental material: Figure S1). We analysed responses from an initial 37 interviews to check internal quality and response validity, and to inform further interviewers' training, before proceeding.

The questionnaire addressed 3 acute respiratory infections: acute otitis media, sore throat, and acute bronchitis. Questions were repeated for each of these infections (in random order to reduce bias), eliciting information from parents about their knowledge and expectations of antibiotic benefits and harms and other treatments; recall of the content of their last medical visit with their child for 1 of these acute respiratory infections (including discussion about antibiotic benefits or harms); shared decision making; and delayed prescribing (receipt of a prescription with the provision that it not be filled immediately). Final questions sought

sociodemographic information. Data were analysed descriptively. Responses to open-ended questions were transcribed, coded, grouped into common themes by 2 researchers (P.D.C and T.C.H), and ranked by frequency. Approval for the study was granted by the Bond University Human Research Ethics Committee.

Results

From 14,505 available random household landline telephone calls, 10,340 numbers were classified as eligible numbers, of which 589 numbers were reachable, and 401 parent interviews were completed (Figure 11). Parent sociodemographic characteristics indicated the large majority of parents were Australian born (77%), female (77%), aged 36 to 45 years (62%), and married or living with a partner (89%) (Table 3). Figure 12 shows that most parents believed that antibiotics help (giving a response of yes or sometimes) for acute otitis media (92%), sore throat (70%), and cough (55%), most commonly by treating the infection and killing bacteria (Supplementary Table: S16). A minority thought antibiotics do not help (Figure 12), most commonly for sore throat and cough, because the illness was viral or other (nonbacterial) in aetiology (Supplementary Table: S17). Similar reasons were also cited commonly when parents were asked why not using antibiotics is sometimes an option (Supplementary Table: S18), along with the response that the illness will resolve without treatment. Some parents believed that not using antibiotics, at least sometimes, was an option (Figure 12), particularly for cough (99%) and sore throat (97%), but less so for acute otitis media (61%). For those who thought antibiotics were necessary, the most common reason given was that the illness would not get better without treatment (Supplementary Table: S19).

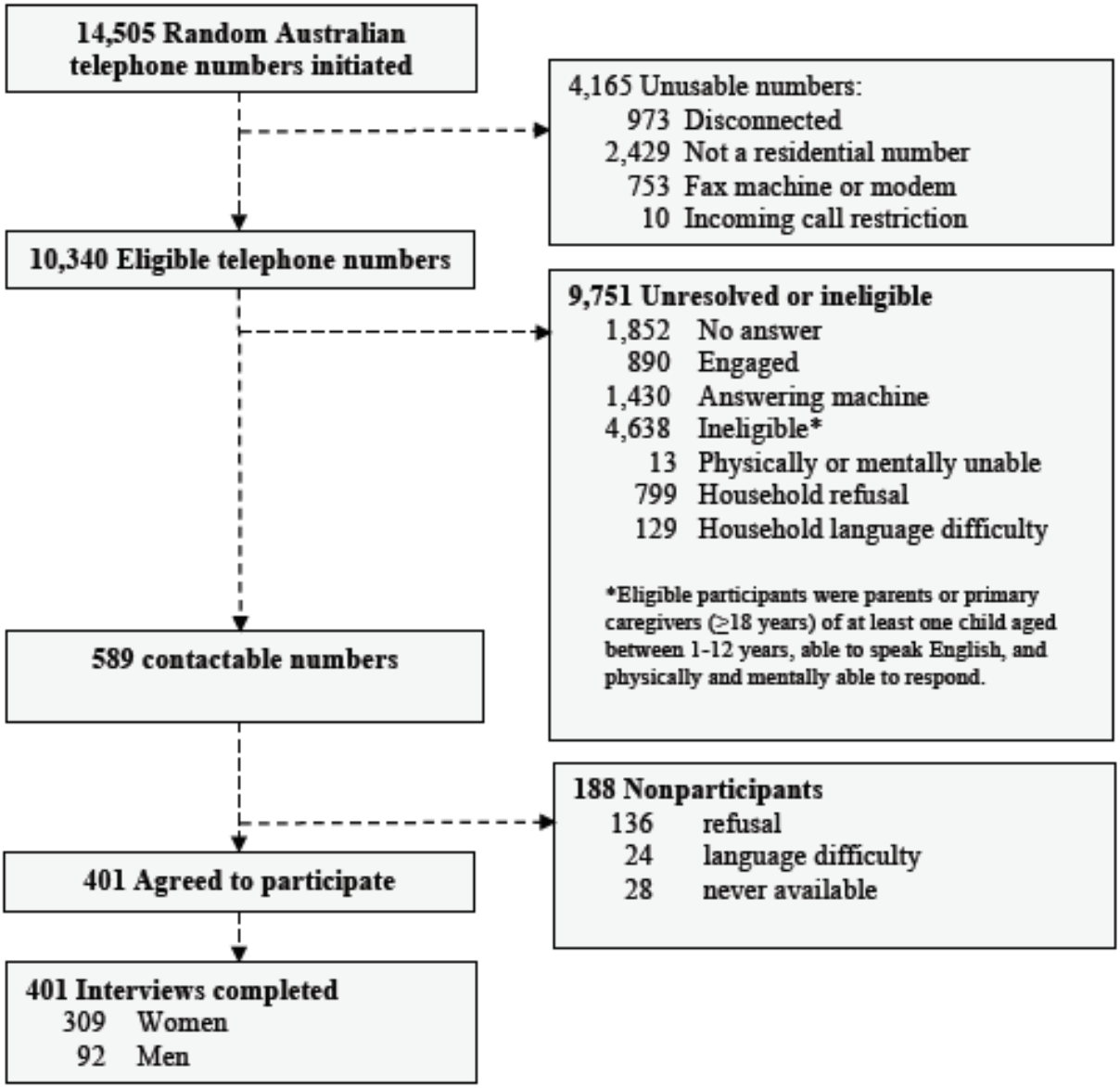


Figure 11: Recruitment of participants for Computer Assisted Telephone Survey

Table 3: Parent characteristics (N = 401)

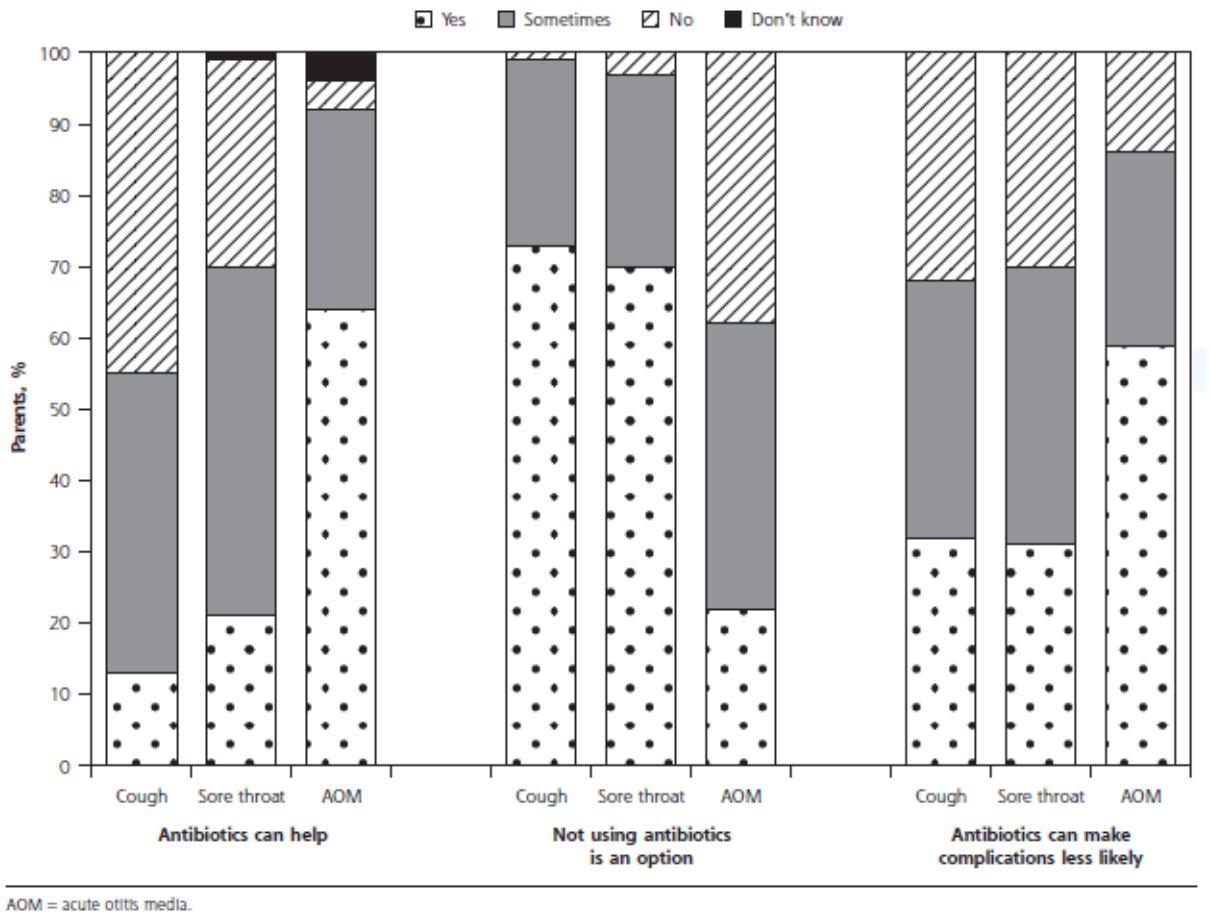
Characteristic	Parents, No. (%)	General Public, %[a]
Female	309 (77)	51
Age-group, y		
≤25	5 (1)	14
26-35	84 (21)	18
36-45	248 (62)	19
46-55	59 (15)	18
≥56	5 (1)	32
Born in Australia	309 (77)	–
English spoken as main language at home	380 (95)	–
Aboriginal or Torres Strait Islander	7 (2)	3
Current living situation		
Married or living with partner	355 (89)	–
Sole caregiving responsibility	39 (10)	–
Other	7 (2)	–
Highest level of education		
Primary school	1 (0)	5
Junior high school	15 (4)	17
Senior high school	50 (13)	38
Trade or apprenticeship	31 (8)	–
Diploma or certificate	103 (26)	21
Bachelor's degree	133 (33)	11
Post-graduate degree	68 (17)	4
Employment status		
Full time (>30 h/wk)	146 (36)	–
Part time (<30 h/wk)	139 (35)	–
Casual employment	29 (7)	–
Not currently in paid employment	86 (21)	5.7
Number of children ≤12 years, mean (SD) [range]	2 (0.85) [1-6]	–
Annual gross household income, $[b]		
<20,000	11 (3)	–
20,001-40,000	24 (6)	–
40,001-60,000	34 (9)	–
60,001-80,000	44 (11)	–
80,001-100,000	63 (16)	–
100,001-140,000	115 (29)	–
140,001-180,000	52 (13)	–
>180,000	33 (8)	–
Health Care Card holder[c]	72 (18)	–
Time since most recent visit to doctor for child with AOM, sore throat, or acute cough, median (IQR), wk	43 (9-104)	–
Age of child at last visit, median (IQR), y	6 (3-8)	–

AOM = acute otitis media; IQR = interquartile range.

[a] From the Australian Bureau of Statistics, for comparison.

[b] In Australian dollars. Mean yearly income was $107,276.

[c] Concession for access to Australian Medicare.



AOM = acute otitis media.

Figure 12: Percentages of parents giving various responses to statements about antibiotic use

For each acute respiratory infection, parents grossly overestimated the benefits of antibiotics in reducing the duration of illness as compared with benefits seen from current empirical evidence (Table 4). Similarly, the minimum reduction in illness duration that parents reported they would want from antibiotics before considering their use (the minimally important difference) grossly exceeded evidence-based estimates, by 5 to 10 times.

Many believed complications from the acute respiratory infections could be avoided by using antibiotics, with highest agreement seen for acute otitis media. The most commonly cited complications were hearing loss, other infections, and perforated eardrum for acute otitis media; other infections and tonsillitis for sore throat; and chest infection and pneumonia for acute cough (Supplementary Table: S20).

Table 4: Parent perceived and actual reduction of illness duration from antibiotic use

Illness Type	Parent-Estimated Benefit, Mean (SD) [Range], Days		Actual Benefit, Based on Empirical Evidence, Mean, Days
	Reduction in Illness Duration From Antibiotics	Minimum Reduction in Duration Before Antibiotics Considered Worth Using	
Acute otitis media	3.0 (1.4) [0-7.0]	3.0 (1.5) [0-7.0]	0.5[5]
Sore throat	2.6 (1.4) [0-7.0]	2.7 (1.6) [0-7.0]	0.5[7]
Acute cough	5.4 (3.1) [0-14.0]	5.0 (3.0) [0-14.0]	<0.5[6]

Table 5: Parents' recall of the last visit with their child to a doctor for an acute respiratory infection

Question	Parents Giving Response, %			
	A Lot	Some	A Little	Not at All
Were reasons you might want an antibiotic for your child discussed with the doctor?	18	26	32	24
Were reasons you might not want to use an antibiotic discussed with the doctor?	12	15	24	48
Would you prefer involvement in future decisions about the use of antibiotics for acute respiratory infections for your child?	75	18	5	2
	Parents Responding "No," %			
Was there any discussion about possible harms of antibiotics?	78			
Were you asked by the doctor whether or not you wanted an antibiotic for your child?	61			
Did the doctor explain that you had a choice about whether or not an antibiotic was prescribed?	61			
Was the decision about antibiotic prescribing shared between you and your doctor?	56			

The large majority of parents, 78%, knew antibiotics could potentially harm. Responses for how included: weakening the immune system (18%); killing good bacteria (11%); harming the balance of gut microbiota (11%); and causing adverse effects such as allergy (13%), gastrointestinal upset (7%), rash (7%), teeth damage/discoloration (7%), and candidiasis (3%). Antibiotic resistance was mentioned by 49%; it was articulated in various ways, some (16%) incorrect, such as the body developing immunity or tolerance to antibiotics.

Overall, 63% of parents reported using treatments other than antibiotics (range of 1 to 4 treatments), including over-the-counter products, simple analgesics, and complementary and alternative medicine. Analgesics and antipyretics (eg, acetaminophen, ibuprofen) were the most commonly used treatments for acute otitis media (82%) and sore throat (71%), and antihistamines and mucolytics were the ones most commonly used for cough (64%). Minor adverse effects were mentioned for many of these alternate treatments (Supplementary Table: S21).

When recalling the most recent visit to a doctor for their child with an acute respiratory infection, 44% of parents reported some discussion (giving a response of some or a lot) about why antibiotics might be used; however, 72% reported little or no discussion about reasons why antibiotics might not be used, and 78% did not remember any discussion about possible antibiotic harms (Table 5). Nearly all (93%) preferred involvement in future decisions about antibiotic use. Slightly more than one-half (58%) of parents recalled being given an antibiotic prescription but instructed not to have it filled immediately (ie, delayed prescribing). Of these parents, 21% filled the prescription, of whom 18% administered the antibiotic to their child.

Discussion

Our principal findings were that most, but not all, parents believe antibiotics are needed for their children's common acute respiratory infections (particularly acute otitis media), and parents have a number of misperceptions about perceived benefit and need. Parents grossly overestimated antibiotic benefits on illness duration, which largely matched the minimally important effect of antibiotics that parents nominated as required for antibiotics to be worth using. Nevertheless, many were aware of potential harms from antibiotics, with some inaccuracies in knowledge identified.

Strengths of our study included the large sample size and careful development of the questionnaire, with inclusion of novel questions about the size of expected benefit. Weaknesses included telephoning only landline numbers and not cell phones, although how this approach

might bias responses is not clear. Also, we had a modest response rate which was nonetheless comparable to those considered satisfactory in other community surveys.[18] Our sample had a higher level of education which may have introduced a bias toward more informed responses, although an exaggeration of misconceptions about antibiotic benefits seems unlikely. Most respondents were women, which probably reflects the inclusion criteria for eligibility (primary caregivers of children at home when the call came through). Recall bias may have distorted questions about the most recent visit to the doctor, and not all parents provided responses to all open-ended questions.

Our findings are largely in line with those of previous studies on parental beliefs about antibiotics' benefits for acute respiratory infections,[19-27] although our study is among the first to quantify them. Of course, such expectations were not homogeneous across parents and illnesses - parents knew that not using antibiotics is sometimes acceptable, consistent with previous findings.[23] Beliefs about the need for antibiotics for acute otitis media were different from those for sore throat and cough, suggesting a role for clinicians in carefully eliciting perceptions and misperceptions that parents might have and tailoring their communication accordingly.[28,29]

About one-half of parents reported antibiotic resistance as a potential harm, similar to proportions found in other cross-sectional studies,[20,28,30] although there was confusion among many about what resistance actually was, as has been reported by others.[19,27,30] Fewer parents mentioned common antibiotic harms consistent with empirical evidence, such as diarrhoea and candidiasis,[31] and some of the complications that parents nominated as being reduced by antibiotic use are not clearly supported by evidence from randomized trials. Parents reported widespread use of alternatives to antibiotics in line with previous findings,[21,27] most of which have no or weak empirical evidence of efficacy,[32,33] with the exceptions being analgesics and antipyretics, and honey for cough.[34]

Antibiotic use for acute respiratory infections is usually a decision that is sensitive to patient preference [35] because the benefit-harm trade-off is marginal. Yet few parents recalled discussing benefits and harms, and the option of forgoing antibiotic use with their clinician. These findings suggest opportunities for improving acute respiratory infection visits by adopting shared decision making, in which the options (using or not using antibiotics) and the benefits and harms of each are explained; parents' concerns, beliefs, expectations, and preferences are explored; and a decision is reached collaboratively.[36] Shared decision making is an effective strategy for reducing antibiotic prescribing for acute respiratory infections in primary care,[37] but widespread implementation is limited. This study found most parents

wanted to be involved in these decisions. Using shared decision making and possibly incorporating delayed prescribing as a presented option [38] in acute respiratory infection visits may enable clinicians and parents to discuss perceived need for and beliefs about antibiotic use and promote informed decision making.

Key words

antibiotics; antimicrobial agents; acute respiratory infections; resistance; acute otitis media; sore throat; cough; decision making; pediatrics

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Supplementary material

Published with article presented in Chapter 5

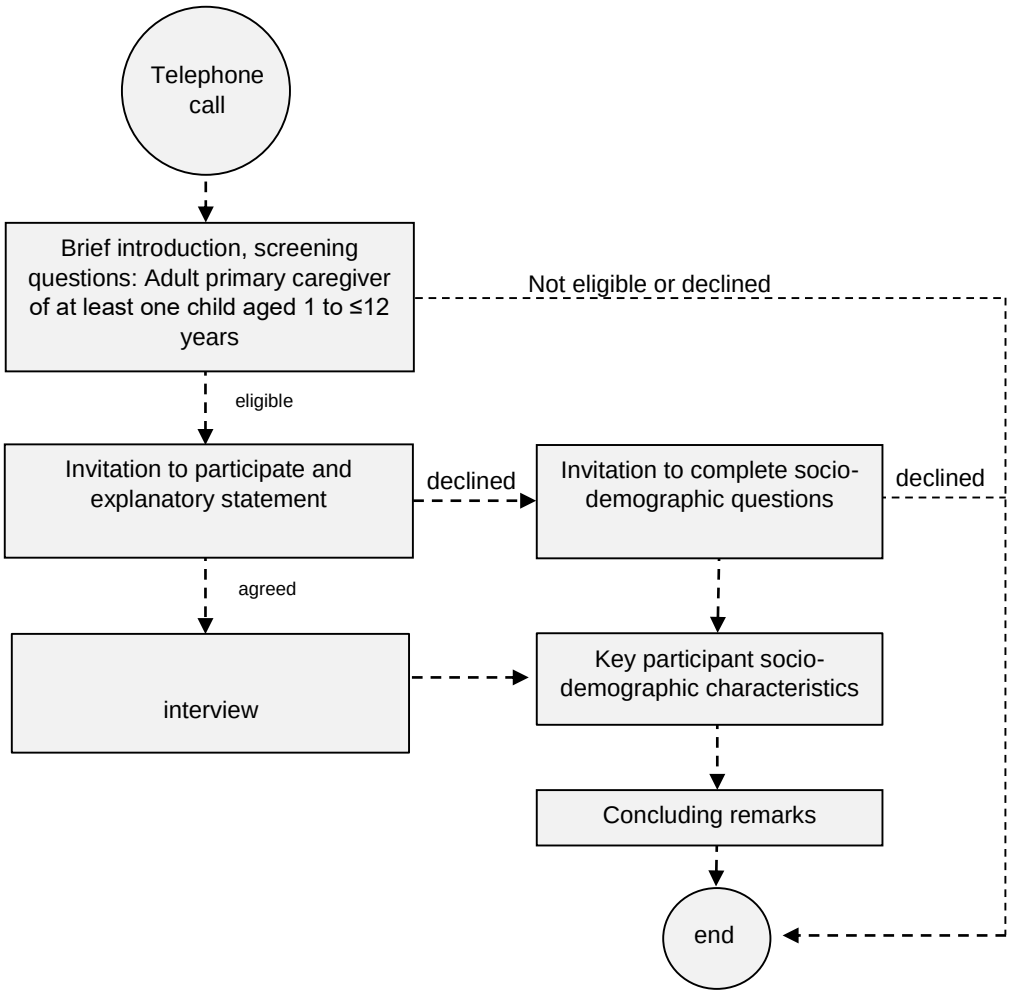


Figure S1: Computer-Assisted Telephone Interview sequence (flow chart)

Notes: only one eligible non-participant agreed to provide brief socio-demographic details.

Table S16: How antibiotics can help, as reported by participants (% of participants nominating reasons how antibiotics can help)

Acute otitis media [a]	**%**	**Sore throat** [b]	**%**	**Acute cough** [c]	**%**
treats 'infection'	38	kills bacteria	38	treats 'infection'	39
kills bacteria	28	treats 'infection'	22	kills bacteria	28
relieves pain	7	treats tonsillitis	15	reduces duration	4
reduces duration	6	reduces duration	4	treats pneumonia	4
reduces inflammation	5	treats sore throat	4	treats acute cough	3
treats AOM	4	treats 'strep throat'	4	treats bronchitis	3
doctor prescribes them	3	relieves pain	3	relieves congestion	3
symptom relief inadequate	3	reduce inflammation	3	relieves pain	3
strengthens immunity	2	kills virus	2	prevents complications	2
prevents complications	1	doctor prescribes them	2	reduces severity	2
kills virus	1	strengthens immunity	1	strengthens immunity	2
reduces fever	1	prevents complications	1	treats whooping cough	2
reduces severity	1	treats laryngitis	1	doctor prescribes them	2
		reduces fever	1	kills virus	1
				reduces inflammation	1
				reduces fever	1

a=347 participant responses; b=292 participant responses; c=214 participant responses

Table S17: Why antibiotics cannot help, as reported by participants (% of participants nominating reasons why antibiotics cannot help)

Acute otitis media [a]	**%**	**Sore throat** [b]	**%**	**Acute cough** [c]	**%**
'no benefit'	36	viral or other (non-bacterial) cause	45	viral or other (non-bacterial) cause	52
viral or other (non-bacterial) cause	27	unnecessary	17	'no benefit'	12
ear needs local treatment	18	other treatment options	17	not indicated/ unnecessary	10
not good for body	9	resolves by itself	8	resolves (or body can heal) by itself	9
need to use own immunity	9	need to use own immunity	6	Other available treatment options	8
		no benefit	2	need to use/build own immunity	5
		antibiotic resistance	2	minor illness (unless complications arise)	2
		not good for the body	2	antibiotic resistance	1
		side effects	1	side effects	1

a=11 participant responses; b=115 participant responses; c=175 participant responses

Table S18: Why not using antibiotics is an option, as reported by participants (% of participants nominating reasons why not using antibiotics is an option)

Acute otitis media [a]	**%**	**Sore throat** [b]	**%**	**Acute cough** [c]	**%**
resolves (or body heals) without treatment	29	viral or 'other' cause (not bacterial, or 'infection')	31	viral, cold/flu, or 'other' cause (non-bacteria) or 'infection'	39
viral or 'other' cause (non-bacterial)	21	other treatment options	22	resolves (or body heals) without treatment	19
mild or short-term (<3 days) illness	20	unnecessary, for mild or short-term (<3 days) illness	18	other treatment options	14
other treatment options (eg. pain and symptomatic relief)	18	resolves (or body heals) without treatment	16	unnecessary, for mild or short-term (>3 days to 2 weeks) illness	10
Doctor's advice	6	antibiotic resistance	4	only if 'dry' cough	4
antibiotic resistance	2	overuse of antibiotics	3	to strengthen immunity	4
weakens immunity	2	to strengthen immunity	3	'no benefit'	3
to strengthen immunity	2	on doctor's advice	1	overuse of antibiotics	2
		weakens immunity	1	antibiotic resistance	2
		'no benefit'	1	weakens immunity	2
				on doctor's advice	1
				cough only a 'symptom'	1

a=233 participant responses; b=444 participant responses; c=412 participant responses

Table S19: Why antibiotics are necessary, as reported by participants (% of participants nominating reasons why antibiotics are necessary)

Acute otitis media [a]	**%**	**Sore throat [b]**	**%**	**Acute cough [c]**	**%**
will not resolve without treatment	42	will not resolve without treatment	57	for ‘chesty’ (not ‘dry’) cough	50
prevents complications	22	prevents complications	29	will not resolve without treatment	25
pain	14	pain	14	prevents complications	25
unaware of other treatment options	5				
more serious illness	5				
reduce illness duration	4				
previous experience	3				
doctor’s advice	3				
ear more ‘delicate’ and ‘close to the brain’	3				

a=192 participant responses; b=7 participant responses; c=4 participant responses

Table S20: Complications perceived as reduced by antibiotic use, as reported by participants (% of participants nominating these complications)

Acute otitis media [a]	%	Sore throat [b]	%	Acute cough [c]	%
Hearing loss	16	other infections	28	'chest' infection	20
other infections (eg. encephalitis, meningitis, or mastoiditis)	15	tonsillitis	20	pneumonia	19
perforated eardrums	14	severe illness	10	other infections	13
pain	11	fever	7	severe illness	12
severe illness	11	eating/swallowing difficulty	6	bronchitis/ bronchiolitis	7
ear 'damage'	6	pain	4	preventing asthma	5
dizziness or loss of balance	5	prolonged illness	4	prolonged illness	4
fever	5	irritability/discomfort	4	breathing difficulties	4
prolonged illness	4	'strep throat'	3	phlegm/congestion	3
irritability/discomfort	3	laryngitis	2	fever	3
pus/fluid buildup	2	inflammation	2	irritability/ discomfort	2
grommets	2	disturbed sleep	2	disturbed sleep	2
convulsions	2	lumps and ulceration	2	'damage' to lung	2
recurrent illness	2	breathing difficulties	1	weakened immunity	1
speech impairment	1	'pus' buildup	1	hospitalization	1
disturbed sleep	1	'weakened' immune system	1	spread of infection to others	1
		recurrent illness	1	organ damage (kidney, brain)	1
		vomiting	1		

a=465 participant responses; b=336 participant responses; c=270 participant responses

Table S21: How other prescription and over-the-counter (including complementary) treatments, and home remedies for ARIs in children, may help or harm, as reported by participants

	AOM	Sore throat	Acute cough
Analgesics/ antipyretics [a]	n=328	n=283	n=155
How it helps	Relieve pain, reduce fever/ inflammation; clears/drains fluid – reduces pressure; sedative; 'placebo' effect; aids sleep/comfort	Relieve pain, reduce fever/ inflammation; treats infection; dries secretions; aids sleep	Reduces symptoms, relieve pain (from cough), reduce fever/inflammation; relieves cough/spasm; sedative – aids sleep; 'placebo' effect
How it may harm	Gastro-intestinal irritation; liver/ kidney damage; seizures; allergic reaction; thins blood; slows heart rate, damages teeth; addiction (codeine); masks symptoms; caution use in asthma	Gastro-intestinal irritation; liver/ kidney damage; seizures; allergic reaction; thins blood; slows heart rate; addiction (codeine); masks symptoms; caution use in asthma	Gastro-intestinal irritation; liver/ kidney damage; masks symptoms; caution use in asthma
Antihistamines [b]**/ mucolytics**	n=6	n=54	n=256
How it helps	Dries mucous; sedating	Clear sinus; relieves congestion; treats infection; reduces cough/post-nasal drip; opens airway; relieves symptoms; reduces inflammation; 'placebo' effect	Soothes throat; stops cough; relieves congestion; clears sinus; reduces symptoms and complications; dries mucous; stops post-nasal drip; aids sleep; supports immunity; 'placebo' effect
How it may harm	-	Vomiting; dehydration	Stomach ulcers; liver/kidney damage; tooth decay; sedative; damage throat 'cells'; masks symptoms
Asthma medication [c]			n=49

	AOM	Sore throat	Acute cough
How it helps	-	-	Relieves cough; opens lungs; reduces inflammation; resolves mucous; prevents asthma
How it may harm	-	-	Induces grogginess/ violence/mood swings, acquired intolerance (prednisone); allergy, stunted growth, dry mouth/bad breath, mouth ulcers (flixotide); increase heart rate/'hyper' reaction (Ventolin)
Topical ear drops/swabs/ candles [d]	n=39		
How it helps	Relieve pain, reduce fever/inflammation; treats infection; dries fluid - reduces pressure; discourages bacterial growth; reduces symptom severity/duration	-	-
How it may harm	Allergic reaction; may sting; reduce 'ear sensitivity'	-	-
Topical throat sprays/lozenges		n=135	n=36
How it helps	-	Reduce symptom severity/duration; relieves/numbs pain; 'coats'/lubricates throat; reduce inflammation; treats infection; aids sleep; 'placebo' effect	-
How it may harm	-	Diarrhoea; drowsiness; allergy; liver damage; tooth decay; mask symptoms	-
Drinks/teas [e]	n=1	n=53	n=33
How it helps	Relieves pain/ congestion	Soothe/'clear' throat, relieve congestion; antibacterial (eg. honey, lemon); support immunity (eg. ginger); reduce symptoms	-
How it may harm	-	-	-
Honey (Manuka/other)		n=24	n=12

	AOM	Sore throat	Acute cough
How it helps	-	Reduces pain/inflammation; supports immunity; 'placebo' effect; reduces duration (anti-bacterial properties)	Reduces symptom severity/duration and inflammation; resolves congestion; antiviral/ antibacterial properties
How it may harm	-	Allergy; teeth decay	_
Gargles [f]	n=1	n=57	n=4
How it helps	Treats infection (iodine) /prevents spread to ear/nose	Treats infection; reduce symptom severity/duration (eg. pain)	Treats infection (saline)
How it may harm	-	-	-
Nasal sprays [g]	n=3	n=1	n=4
How it helps	Helps drain/clear mucous	Reduce pain	Resolves congestion; stops post-nasal drip
How it may harm	-	-	-
Chest rubs		n=7	n=21
How it helps	-	Opens airways; relieves congestion; soothes throat; aids sleep	Opens airways to assist breathing; clears sinus; resolve congestion; stops post-nasal drip; reduces symptoms; aids sleep; 'placebo' effect
How it may harm	-		Skin irritation
Vaporiser/ humidifier			n=38
How it helps	-	-	Reduces cough; clears chest/sinus; resolves congestion; 'moistens' airways; aids sleep
How it may harm	-	-	-
Heat therapy [h]	n=6		
How it helps	Soothes; reduces pain; helps soften/drain 'hard' blockages	-	-
How it may harm	May burn	-	-
CAM therapies [i]	n=5	n=9	n=11
How it helps	Reduce symptom severity/duration; supports/builds immune system	Reduce symptom severity/duration; supports/builds immune system	Alternative 'cure'; builds immune system
How it may harm	-	-	-
Herbal extracts [j]	n=2	n=16	n=16

	AOM	Sore throat	Acute cough
How it helps	Reduce symptom severity/duration; supports/builds immune system	Treats infection; reduce symptom severity/duration; supports/builds immune system; reduces mucous	Reduces symptom severity/duration; relieves congestion
How it may harm	-	-	-
Vitamins/ Supplements [k]	n=10	n=40	n=34
How it helps	Reduce symptom severity/duration; supports/builds immune system	Reduce symptom severity/duration; supports/builds immune system; treats vitamin deficiency	Reduces symptoms; treat infection; builds immunity; restores healthy bacteria
How it may harm	Gastro-intestinal irritation	Diarrhoea; tooth decay	Diarrhoea

a=includes single and combination products (eg. paracetamol, ibuprofen, paracetamol/codeine, paracetamol/codeine/promethazine, paracetamol/phenylephrine)
b=antihistamines includes promethazine
c=includes ventolin, flixotide, seritide, singulair, prednisone/prednisolone
d=includes prescribed (eg. antibacterial, antifungal), over-the-counter (eg. aqua-ear, auralgan, hydrogen peroxide), home remedies (eg. garlic oil, caster oil, coconut oil/garlic, onion tea/olive oil, olive oil), and unspecified.
e=includes herbal teas (eg. honey/ginger, ginger, tumeric, white marshmallow, garlic/ginger/lemon/honey, walnut) and drinks (eg. apple cider vinegar, orange juice, lemon/honey)
f=includes iodine, saline, aspirin, paracetamol, betadine
g=includes over-the-counter (eg. saline, fess, otrivin)
h=including wheat or flannel bag
i= homoeopathy/naturopathy/herbal medicine/traditional chinese medicine
j= includes black elderberry, echinacea, olive leaf, ivy leaf, aniseed, grapefruit seed
k=includes vitamins (eg. vitamin C, multivitamins, antioxidants) and supplements (eg. wheatgrass, watermelon tablets, probiotics, immune support tablets, fish oil tablets, garlic, tumeric, horseradish/garlic/zinc)

Appendix

Survey questionnaire

Q1
To begin with, using a scale of 'Always', 'Most of the time', 'Sometimes', 'Occasionally' and 'Never', how often do you typically use antibiotics for your child's…

	Always	Most of the time	Sometimes	Occasionally	Never
Q1A Middle ear infection	□ 01	□ 02	□ 03	□ 04	□ 05
Q1B Sore throat	□ 01	□ 02	□ 03	□ 04	□ 05
Q1C Cough	□ 01	□ 02	□ 03	□ 04	□ 05

Q2A
Do you think antibiotics can help for a **middle ear infection**?

01 Yes
02 Sometimes
03 No
98 Don't know/unsure

Q2A_1
How do you think antibiotics can help for a **middle ear infection**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q2A_2
Why do you think antibiotics can't help with a **middle ear infection**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q2B
Do you think antibiotics can help for a **sore throat**?

01 Yes
02 Sometimes
03 No
98 Don't know/unsure – *Do not read out*

Q2B_1
How do you think antibiotics can help for a **sore throat**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q2B_2
Why do you think antibiotics can't help with a **sore throat**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q2C
Do you think antibiotics can help for a **cough**?

01 Yes
02 Sometimes
03 No
98 Don't know/unsure – *Do not read out*

Q2C_1
How do you think antibiotics can help for a **cough**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q2C_2
Why do you think antibiotics can't help with a **cough**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3A
Do you think **NOT** using antibiotics is an option for managing a **middle ear infection** in children?

01 Yes
02 Sometimes
03 No

Q3A_1
Why do you think **not using** antibiotics is an option for managing a **middle ear infection**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3A_2
Why do you think antibiotics **are necessary** for managing a **middle ear infection**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3B
Do you think **NOT** using antibiotics is an option for managing a **sore throat** in children?

01 Yes
02 Sometimes
03 No

Q3B_1
Why do you think **not using** antibiotics is an option for managing a **sore throat**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3B_2
Why do you think antibiotics **are necessary** for managing a **sore throat**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3C
Do you think **NOT** using antibiotics is an option for managing a **cough** in children?

01 Yes
02 Sometimes
03 No

Q3C_1
Why do you think **not using** antibiotics is an option for managing a **cough**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q3C_2
Why do you think antibiotics **are necessary** for managing a **cough**?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q4
We would like to know how much benefit you expect from antibiotics when your child has a middle ear infection, sore throat or cough, such as shortening the length of your child's illness.

If your child has a **middle ear infection** that was to last for about **7 days** without any treatment…

How much time (in days or hours) do you think antibiotics will shorten the length of your child's **middle ear infection**?

Q4A Days: [Include Open-end]
Q4B Hours: [Include Open-end]
Q4C 98 Don't know/unsure – *Do not read out*

Q5
What is the minimum amount of time (in days or hours) you would want antibiotics to shorten the length of your child's **middle ear infection** for you to consider using them?

Q5A Days: [Include Open-end]
Q5B Hours: [Include Open-end]
Q5C 98 Don't know/unsure – *Do not read out*

Q6
We would like to know how much benefit you expect from antibiotics when your child has a middle ear infection, sore throat or cough, such as shortening the length of your child's illness.

If your child has a **sore throat** that was to last for about **7 days** without any treatment…

How much time (in days or hours) do you think antibiotics will shorten the length of your child's **sore throat**?

Q6A Days: [Include Open-end]
Q6B Hours: [Include Open-end]
Q6C 98 Don't know/unsure – *Do not read out*

Q7
What is the minimum amount of time (in days or hours) you would want antibiotics to shorten the length of your child's **sore throat** for you to consider using them?

Q7A Days: [Include Open-end]
Q7B Hours: [Include Open-end]
Q7C 98 Don't know/unsure – *Do not read out*

Q8
We would like to know how much benefit you expect from antibiotics when your child has a middle ear infection, sore throat or cough, such as shortening the length of your child's illness.

If your child has a **cough** that was to last for about **14 days** without any treatment…

How much time (in days or hours) do you think antibiotics will shorten the length of your child's **cough**?

Q8A Days: [Include Open-end]
Q8B Hours: [Include Open-end]
Q8C 98 Don't know/unsure – *Do not read out*

Q9
What is the minimum amount of time (in days or hours) you would want antibiotics to shorten the length of your child's **cough** for you to consider using them?

Q9A Days: [Include Open-end]
Q9B Hours: [Include Open-end]
Q9C 98 Don't know/unsure – *Do not read out*

Q10A
Do you think antibiotics can make complications less likely for a child with a **middle ear infection**?

01 Yes
02 Sometimes
03 No

Q10A_1
What complications are less likely?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q10B
Do you think antibiotics can make complications less likely for a child with a **sore throat**?

01 Yes
02 Sometimes
03 No

Q10B_1
What complications are less likely?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q10C
Do you think antibiotics can make complications less likely for a child with a **cough**?

01 Yes
02 Sometimes
03 No

Q10C_1
What complications are less likely?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q11
Do you think there can be any harm from using antibiotics with children?

01 Yes
02 Sometimes
03 No

Q11_1
What are they?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q11_2
Why not?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q12A
What other prescription and over-the-counter medicines (including complementary medicines) do you use when your child has a **middle ear infection**?

01 Treatment 1: [Include Open-end]
02 Treatment 2: [Include Open-end]
03 Treatment 3: [Include Open-end]
04 Treatment 4: [Include Open-end]
05 Does not use other medicines – *Do not read out*

Q13A_1
In what way does [Pipe text from Q12A:01] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13A_2
In what way does [Pipe text from Q12A:02] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13A_3
In what way does [Pipe text from Q12A:03] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13A_4
In what way does [Pipe text from Q12A:04] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q14A
Do you think there are any harms from using [Pipe text from Q12A:01 if only 1 nominated treatment OR If more than 1 nominated treatment pipe: "any of these"]?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q12B
What other prescription and over-the-counter medicines (including complementary medicines) do you use when your child has a **sore throat**?
01 Treatment 1: [Include Open-end]
02 Treatment 2: [Include Open-end]
03 Treatment 3: [Include Open-end]
04 Treatment 4: [Include Open-end]
05 Does not use other medicines – *Do not read out*

Q13B_1
In what way does [Pipe text from Q12B:01] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13B_2
In what way does [Pipe text from Q12B:02] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13B_3
In what way does [Pipe text from Q12B:03] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13B_4
In what way does [Pipe text from Q12B:04] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q14B
Do you think there are any harms from using [Pipe text from Q12B:01 if only 1 nominated treatment OR If more than 1 nominated treatment pipe: "any of these"]?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q12C
What other prescription and over-the-counter medicines (including complementary medicines) do you use when your child has a **cough**?

01 Treatment 1: [Include Open-end]
02 Treatment 2: [Include Open-end]
03 Treatment 3: [Include Open-end]
04 Treatment 4: [Include Open-end]
05 Does not use other medicines – *Do not read out*

Q13C_1
In what way does [Pipe text from Q12A:01] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13C_2
In what way does [Pipe text from Q12A:02] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13C_3
In what way does [Pipe text from Q12A:03] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q13C_4
In what way does [Pipe text from Q12A:04] help?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q14C
Do you think there are any harms from using [Pipe text from Q12C:01 if only 1 nominated treatment OR If more than 1 nominated treatment pipe: "any of these"]?
01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q15
When any treatment or health product uses the phrase 'clinically proven', what do you think this means?

01 [Include Open-end]
98 Don't know/unsure – *Do not read out*

Q16
For the next set of questions, please think back to the last time that **you** took your child to the doctor for a middle ear infection, sore throat or cough.

Approximately how long ago was this?
Q16D Days: [Include Open-end]
Q16A Weeks: [Include Open-end]
Q16B Months: [Include Open-end]
Q16Y Years: [Include Open-end]]
Q16C 03 Have not taken child to doctor for these

Q17
About what age was your child at this time?
Q17A Weeks: [Include Open-end]
Q17B Months: [Include Open-end]
Q17C Years: [Include Open-end]

Q18
How much did you and the doctor discuss the reason you might want to use antibiotics with your child?
01 A lot
02 Some
03 A little
04 Not at all
98 Don't know/don't remember – *Do not read out*

Q19
Using that same scale, how much did you and the doctor discuss the reasons you might **not** want to use antibiotics with your child?
01 A lot
02 Some
03 A little
04 Not at all
98 Don't know/don't remember – *Do not read out*

Q20
Did the doctor discuss possible harms of antibiotics with you?
01 Yes (please specify what harms): [Include Open-end]
02 No
98 Don't know/don't remember – *Do not read out*

Q21
Did the doctor explain that you could **choose** whether or not to use antibiotics?
01 Yes
02 No
98 Don't know/don't remember – *Do not read out*

Q22
Did the doctor ask you whether or not you wanted your child to have antibiotics?

01 Yes
02 No
98 Don't know/don't remember – *Do not read out*

Q23
Who made the final decision about the use of antibiotics to treat your child's illness? Was it…

01 Mainly you
02 Mainly the doctor
03 You and the doctor made the decision together
98 Don't know/don't remember – *Do not read out*

Q24
In the future, how much do you typically want to be involved in decisions about the use of antibiotics to treat your child's illness?

01 A lot
02 Some
03 A little
04 Not at all

Q25
Has your doctor ever given a prescription for antibiotics and said **not** to give them to your child **unless** they became worse or did not get better?

01 Yes
02 Sometimes
03 No
98 Don't know/don't remember – *Do not read out*

Q25A
Did you fill the prescription?

01 Yes
02 No
98 Don't know/don't remember – *Do not read out*

Q25B
Did you end up using the antibiotics for your child?

01 Yes, what led to you deciding to use them? [Include open-end]
02 No
98 Don't know/don't remember – *Do not read out*

Q26
Have you ever used antibiotics for your child, that they or a family member were previously prescribed for a similar illness, **before** or without taking your child to see a doctor?

01 Yes
02 Sometimes
03 No
98 Don't know/don't remember – *Do not read out*

Q27
This next question is broader and not just about antibiotics or respiratory infections. It is about how your doctor communicates with you about research that helps them to know about the best care for your child.

I'm going to read you 6 statements and ask you to choose three statements in order of preference that would make you feel the most confident about the information your doctor explains to you:

01 What the research shows
02 Guidelines developed by national medical experts about what works best
03 Best practices in the medical field
04 What medical science shows about each option's benefits and risks
05 What is proven to work best
06 The most-up-to-date medical evidence, including information about the risks and benefits, about what works best

Q28
What is the respondent's gender?

01 Female
02 Male

Q29
Can you tell me which age group you are in?

01 18 – 25
02 26 – 35
03 36 – 45
04 46 – 55
05 56 or greater
99 Refused – *Do not read out*

Q30
Which country were you born in?

01 Australia
02 Other (please specify): [Include Open-end]
98 Don't know – *Do not read out*
99 Refused – *Do not read out*

Q31
What is the main language spoken in your home?

01 English
02 Other (please specify): [Include Open-end]

Q32
Do you identify as Aboriginal or Torres Strait Islander?

01 Yes
02 No
98 Don't know – *Do not read out*
99 Refused – *Do not read out*

Q33
What is your current living situation? Are you…

01 Married or living with partner
02 The only adult in the household who has caregiving responsibility for the child/ren
03 Other
99 Refused – *Do not read out*

Q34
What is the highest level of education you have completed? Was it…

01 Primary school
02 Junior high school
03 Senior high school
04 Trade or apprenticeship
05 Diploma or certificate
06 Bachelor's degree
07 Post-graduate degree
99 Refused – *Do not read out*

Q35
What is your current employment status? Are you…

01 Full-time employed (30 or more hours per week)
02 Part-time employed (less than 30 hours per week)
04 Casually employed
03 Not currently in paid employment
99 Refused – *Do not read out*

Q36
What is your postcode?

01 [Include Open-end]
98 Don't know – *Do not read out*
99 Refused – *Do not read out*

Q37
How many children 12 years and under usually reside in the household?

01 1 child
02 2 children
03 3 children
04 4 children
05 5 children
06 6 children
07 7 children
08 8 children
09 9 children
10 10 children
99 Refused – *Do not read out*

Q38
What are the ages of your child or children aged 12 years old and under?

Q38_1 Child 1: [Include Open-end]
Q38_2 Child 2: [Include Open-end]
Q38_3 Child 3: [Include Open-end]
Q38_4 Child 4: [Include Open-end]
Q38_5 Child 5: [Include Open-end]
Q38_6 Child 6: [Include Open-end]
Q38_7 Child 7: [Include Open-end]
Q38_8 Child 8: [Include Open-end]
Q38_9 Child 9: [Include Open-end]
Q38_10 Child 10: [Include Open-end]
Q38_11 99 Refused – *Do not read out*

Q39
We would also like to know how income relates to access to healthcare and medicines.

What is your annual household income before tax (from all sources)? Is it…

01 Less than $20,000
02 $20,001 - $40,000
03 $40,001 - $60,000
04 $60,001 - $80,000
05 $80,001 - $100,000
06 $100,001 - $140,000
07 $140,001 – $180,000
08 More than $180,000
98 Don't know – *Do not read out*
99 Refused – *Do not read out*

Q40
And finally, do you hold a current government (Department of Human Services) Health Care Card?

01 Yes
02 No
98 Don't know – *Do not read out*
99 Refused – *Do not read out*

Thank you very much for your time. Your responses have been very helpful to this research.

Chapter 6

Development of Three Brief Patient Decision Aids About Antibiotic Use for Acute Otitis Media, Sore Throat, and Acute Bronchitis

Preamble to Chapter 6

One of the key findings of Study 2 (Chapter 5)[1] was that a number of parents have misperceptions about the perceived benefit of and need for an antibiotic in common childhood ARIs, particularly for AOM. This study is the first to quantify parents' overestimation of antibiotics benefit on illness duration. It also found that many parents were aware of the potential for harms from antibiotics, including both side-effects and antibiotic resistance, but had some misunderstandings about what the harms were and consequences of them. Despite evidence that there is only a marginal benefit-to-harm trade-off when antibiotics are used for these conditions, therefore making it a preference-sensitive decision and ideal for shared decision making, more than two-thirds of parents reported little to no discussion with their doctor about the option of not using antibiotics, why they may not be necessary, or the possible harms associated with their use. Nearly all parents preferred greater involvement in future treatment decisions when their child has an ARI.

While Study 1 (Chapter 4) [2] found that interventions which aim to facilitate shared decision making can reduce antibiotic prescribing for ARIs in primary care, the interventions included in the review were typically complex, multi-component, intensive, and unlikely to be readily implemented in settings beyond the original trials. Moreover, only one trial included only children and their parents, and few others included children at all[2], despite their higher incidence of antibiotics for ARIs.[3]

Decision aids, which are the most simple and low intensive intervention among those evaluated in the trials included in the review, were used as an intervention component in one pilot trial [4] and main trial.[5] Decision aids are tools which can be used to support shared decision making.[6] However, there has been little research on their use for antibiotic use in ARIs. The decision aid used in existing trial [5] was a single aid which addressed multiple ARIs, its acceptability to patients had not been evaluated, and it was primarily aimed at clinicians as it contained information about diagnostic probabilities. This trial,[4] as highlighted in Study 1 (Cochrane review [2]) also found that the decision aid had no significant effect on patients' intention to engage in shared decision making. A subsequent study concluded that the intervention needed to be more patient-targeted,[7] pointing to an important research gap.

The findings of Studies 1 and 2, and other relevant literature that was discussed in Chapter 2, indicated a need for brief, patient-focused, evidence-based decisions aids to help support shared decision making about antibiotic use for common ARIs. This chapter describes

the development process and rationale for each component of three such decision aids that were developed for AOM, sore throat, and acute bronchitis.

Development of the patient decision aids

The patient (parent) decision aids were systematically developed in accordance with the updated review of International Patients Decision Aid Standards (IPDAS) international quality criteria [8] and development processes.[9] A summary of how the decision aids meet the PDAS criteria is presented in Table 1. Of the 7 criteria stated by IPDAS for inclusion as a patient decision aid, all criteria are met. Of the 9 criteria to lower the risk of making a biased decision, 8 criteria are met. The criterion about disclosing whether the authors of the aid may gain or lose based on the choices that people make was not able to be added at this initial stage of development and evaluation, but it will be added in the final version of the tool that the developers will not benefit or lose from decisions about antibiotic use. Funding for this PhD research was supported by a PhD scholarship that was part of a broader research grant from the National Health and Medical Research Council of Australia to the supervisory team and various government agencies are involved with the research program. Hence, approval to add such statements will be sought from all relevant stakeholders once all phases of decision aid evaluation have been completed.

Table 6: International Patient Decision Aid Standards (IPDAS) checklist

Criteria to be defined as a patient decision aid	Answer
1. The decision aid describes the condition (health or other) related to the decision.	**Yes**
2. The decision aid describes the decision that needs to be considered (the index decision).	**Yes**
3. The decision aid identifies the target audience.	**Yes**
4. The decision aid lists the options (health care or other).	**Yes**
5. The decision aid has information about the positive features of the options (e.g. benefits, advantages).	**Yes**
6. The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).	**Yes**
7. The decision aid helps patients clarify their values for outcomes of options by: a) asking people to think about which positive and negative features of the options matter most to them AND/OR b) describing each option to help patients imagine the physical, social, and /or psychological effect.	**Yes**

Criteria to lower the risk of making a biased decision	Answer
1. The decision aid makes it possible to compare the positive and negative features of the available options.	**Yes**
2. The decision aid shows the negative and positive features of the options with equal detail.	**Yes**
3. The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	**Yes**
4. The decision aid (or available technical documents) reports funding sources for development.	**Yes**
5. The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	**No**
6. The decision aid includes authors/developers' credentials or qualifications.	**Yes**
7. The decision aid reports the date when it was last updated.	**Yes**
8. The decision aid (or available technical document) reports readability levels.	**Yes**
9. The decision aid provides references to scientific evidence used.	**Yes**

Other criteria for decision aids about screening or testing	Answer
1. The decision aid has information about what the test is designed to measure.	**NA**
2. The decision aid describes possible next steps based on the test results.	**NA**
3. The decision aid has information about the chances of disease being found with and without screening.	**NA**
4. The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done.	**NA**

NA=Not Applicable

Other criteria indicating quality	Answer
1. The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	**Yes**
2. The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).	**NA**
3. The information about outcomes of options (positive and negative) includes the chances they may happen.	**Yes**
4. The decision aid presents probabilities using event rates in a defined group of people for a specified time.	**Yes**
5. The decision aid compares probabilities of options over the same period of time.	**Yes**
6. The decision aid uses the same scales in diagrams comparing options.	**Yes**
7. Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	**Yes**
8. The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.	**Yes**
9. People who were facing the decision field tested the decision aid.	**Yes**
10. Field testing showed that the decision aid was acceptable to users (the general public & practitioners).	**Yes**
11. Field testing showed that people who were undecided felt that the information was presented in a balanced way.	**Yes**
12. There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.	**Yes**
13. There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.	**Yes**

NA=Not Applicable

*From the Decision Aid Library Inventory (https://decisionaid.ohri.ca/cochinvent.php)

The content of each decision aid was informed by rigorous and current empirical evidence, including: previous systematic reviews of qualitative studies on parent and clinician influences on antibiotic prescribing behaviours;[10,11] findings from the Australian-wide survey exploring parents' expectations of antibiotic benefits and harms for childhood ARIs (Study 2, Chapter 5)[12] and qualitative and observational research which had explored parents' beliefs and expectations of antibiotics for these conditions;[1,10,13-16] relevant Cochrane systematic reviews to quantify benefits of antibiotics for acute otitis media,[17] acute pharyngitis,[18] and acute bronchitis,[19] and a meta-analysis of antibiotic harms;[20] and risk communication research [21,22] for the optimal presentation of numerical, graphical and narrative benefit and harm data. Instruments were developed in English only. The readability was assessed using the SMOG index,[23] a widely used tool for assessing the readability of written health materials aimed at patients.[24] The developed decision aids were assessed as being at reading level suitable for sixth grade readers, which is at the recommended fifth to sixth grade level.[25]

A key feature of the format was that the aids needed to be brief to facilitate their use in a 10-minute general practice consultation - a requirement that emerged during piloting with clinicians. The decision aid was designed to be short enough to so that all content fitted onto a single double-sided A4 page. This would enable it to be used as a laminated hard copy resource by clinicians and if desired by clinicians or parents/patients, able to be printed and given as a take home resource.

Each patient decision aid prototype was pilot tested with parents, an advisory group of clinicians, and researchers with clinical and research expertise in primary care, ARIs, evidence-based practice, and shared decision making. After modifications were made based on feedback, two further rounds of comments were invited and subsequent minor changes made. The aids were then further pilot tested with a different, purposeful sample of eligible parents (n=12) and clinicians (n=6). At this stage, the aids were considered ready to be tested in a randomised trial in a community sample of parents to evaluate whether they improved parents' informed choice about antibiotic use for these ARIs, as well as to formally examine the acceptability and usability of the materials. This trial (Study 3) is described in Chapter 7.[12]

Annotated example of the decision aids

An annotated version of the patient decision aid format for AOM is presented as an example in Figure 13. The rationale for the inclusion of each element is presented below. The decision aids for sore throat and acute bronchitis used the same format and are presented in Figures 2 and 3 respectively.

1. Wording of the title

The title frames the scope and purpose of the decision aid, states the specific health condition and decision, and specifies who the target users of the decision aid are. It emphasises that the decision should be a shared one between patients/parents and their doctor. For the AOM decision aid, the emphasis was on parents as it is mainly children who experience AOM.[25] However for the other two aids, it could be either children or adults and feedback from the pilot groups indicated that having a 'child' and 'adult' version of these two aids should be avoided.

2. Listing of two options

Not taking antibiotics is explicitly flagged as an option, as in Study 2 (Chapter 5),[1] one finding was that many parents were unaware that not using an antibiotic was an option.

3. Presentation of antibiotic benefits as the decrease in symptom duration *and* the number of people who benefit

In Study 2 (Chapter 5),[1] one finding was that parents grossly overestimated the benefit of antibiotics on symptom duration in comparison to what the evidence from systematic reviews shows they actually provide. Based on the relevant Cochrane systematic review for each aid, evidence for the benefit of antibiotic use on the average symptom reduction was presented, compared with the option of not using an antibiotic (that is, the difference in the average duration of symptoms) (see box 3a in Figure 13). During piloting of the aids, some participants preferred the inclusion of benefit data about effect on symptom duration, whereas others preferred to see the absolute number of people who benefit and do no benefit from taking antibiotics. Some participants indicated they liked to see both. Based on this feedback, antibiotic benefits were presented in both formats in the aids. Systematic review evidence [26-28] informed numerical presentation of the number of people who get better with antibiotic use, compared to those who do not take an antibiotic (ie. absolute difference), using a simple frequency format that incorporated both a number and time period (ie. x in 100 people will be better by 2-3 days) (see box 3b, Figure 13).

4. Graphic displays: bar graphs for the benefits of antibiotics on symptom reduction, and icon arrays to illustrate the absolute benefits and harms of antibiotics

The graphical presentation of numerical data improves patients' accuracy of the numerical estimates of decision outcomes, although the optimal graphical display is dependent on the nature of data to be presented.[22] A recent randomised trial that found, compared with five other graphical displays, bar graphs showing the effects of treatment on symptom duration helped more people make decisions about seeking treatment for sore throat that were consistent with their values.[21] These findings underpinned the use of horizontal bar charts in the decision aids to graphically present the difference in the duration of symptoms from using an antibiotic or not (box 3a, Figure 1).

Icon arrays include the numerator and denominator in a single diagram, and are recommended method for helping people to understand numerical probabilities.[22] Icon arrays were used to graphically represent the absolute benefit (that is, the number of children that will get better after 2-3 days) of taking an antibiotic or not, and highlighting the absolute difference between the two options (box 3b, Figure 13). The numerical presentation of common antibiotic harms (vomiting, diarrhoea, and rash) used an identical format, although a contrasting colour was used, and was informed by the findings of a recent systematic review and meta-analysis [20] (box 4, Figure 13). Other downsides of antibiotic use relating to the need to remember to take the antibiotics, their cost, and the risk of antibiotic resistance are presented narratively. The bar graphs and icon arrays were iteratively revised using feedback received during piloting with clinicians, researchers, and consumers.

5. Statement about source of the evidence

Inclusion of information about the source and quality of the evidence was based on the findings and conclusion of a randomised trial to support the public's understanding of this element (box 5, Figure 13).[29]

6. Evidence-based treatments for symptom management

In Study 2 (Chapter 5) [1] parents reported widespread use of over-the-counter medicines, complementary and alternative products, or home remedies as treatment alternatives to antibiotics or symptom management. Previous observational findings support that parents are equally grateful about recommendations for the symptomatic management of a child's ARI.[30] Options for the management of symptoms were included where there was evidence supporting their use.

7. Information about antibiotic resistance, and its importance, particularly to the individual

Study 2 (Chapter 5) [1] found that many parents were aware of antibiotic resistance, although many incorrectly articulated how this occurs. This confirms findings of a systematic review about the public's beliefs and attitudes to antibiotic resistance, which also found misunderstanding of the mechanisms of resistance, and low level of awareness of the consequences of resistance to the individual and the community.[31]

8. Information about when to re-consult if symptoms deteriorate or do not resolve

Important signs and symptoms that might indicate a more serious infection and therefore that patients/parents should re-consult or seek further treatment were included. This is important for safety reasons, regardless of whether a decision was made to use an antibiotic or not.

9. Questions to ask

A modification of the 4-Item SURE questionnaire [32] was included to facilitate parents to ask four questions that reduce decision uncertainty and to help them decide if they have enough information to make a joint decision with their clinician. These questions were modified from the original four because feedback from stakeholders was that the decision aids should align with and incorporate aspects of the national 'Choosing Wisely' initiative which had just been launched in Australia by NPS MedicineWise,[33] and encouraged the public to ask their clinician five questions before undertaking any test or treatments.

10. Footnotes

As per IPDAS criteria, the footnote includes the sources of evidence (in this case, the citation details of the systematic reviews which provided evidence of antibiotic benefit and harms, and where relevant, other treatments for symptomatic management), the decision aid authors, when it was last updated and when it was due for review, and the funding source for development of the aid.

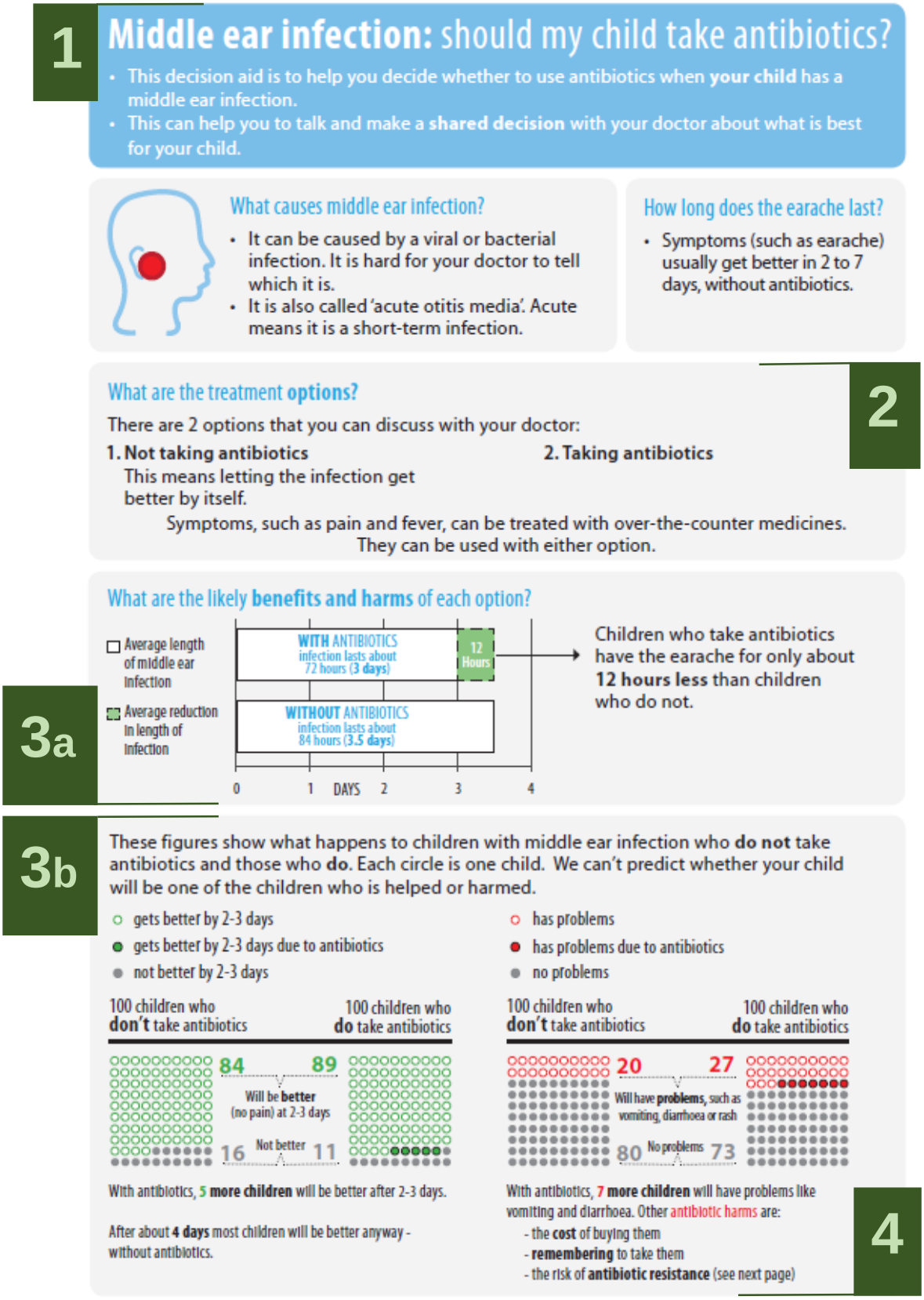


Figure 13: The front side of the two-sided A4-page decision aid for acute otitis media

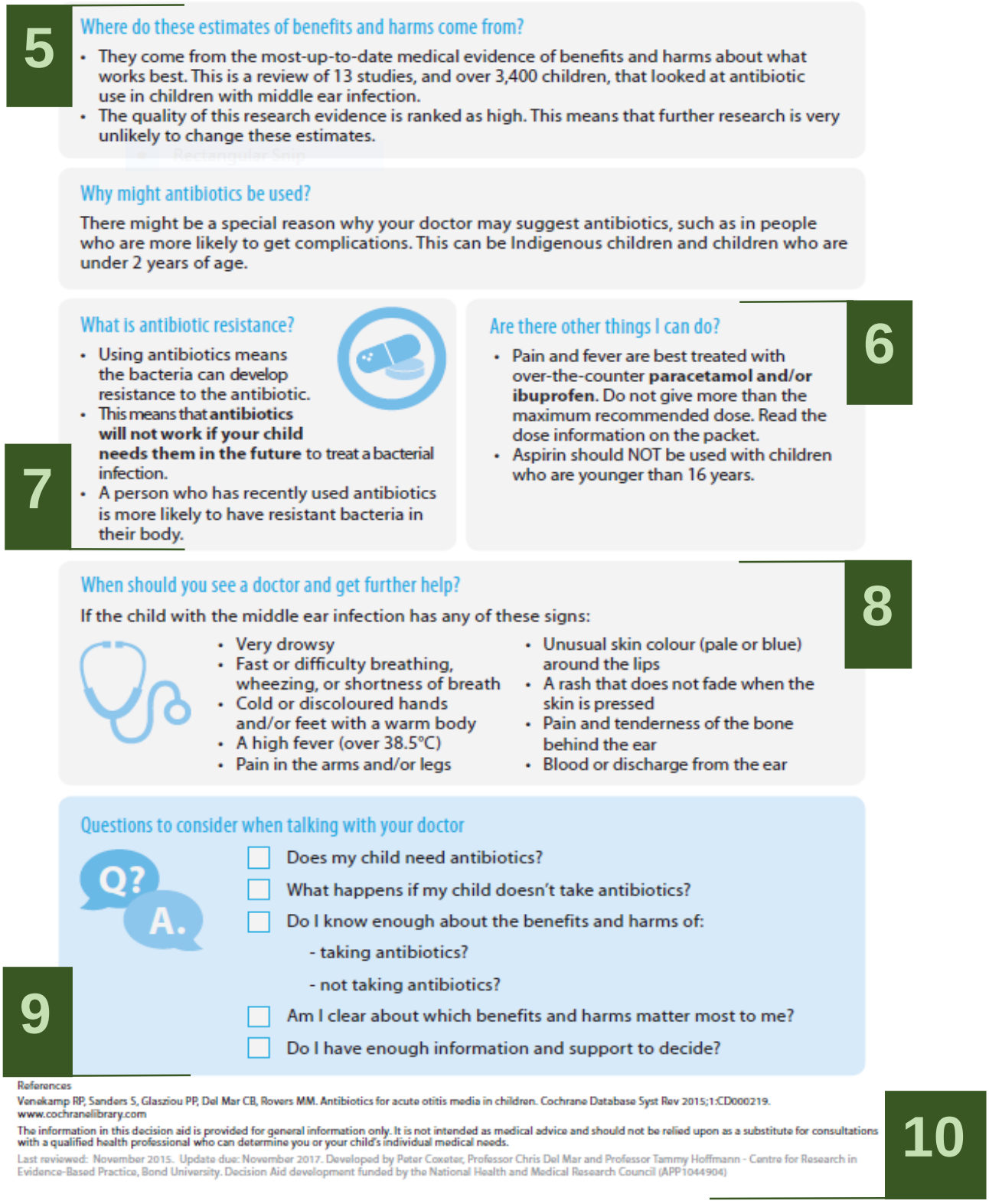


Figure 13 (continued): The back side of the two-sided A4-page decision aid for acute otitis media

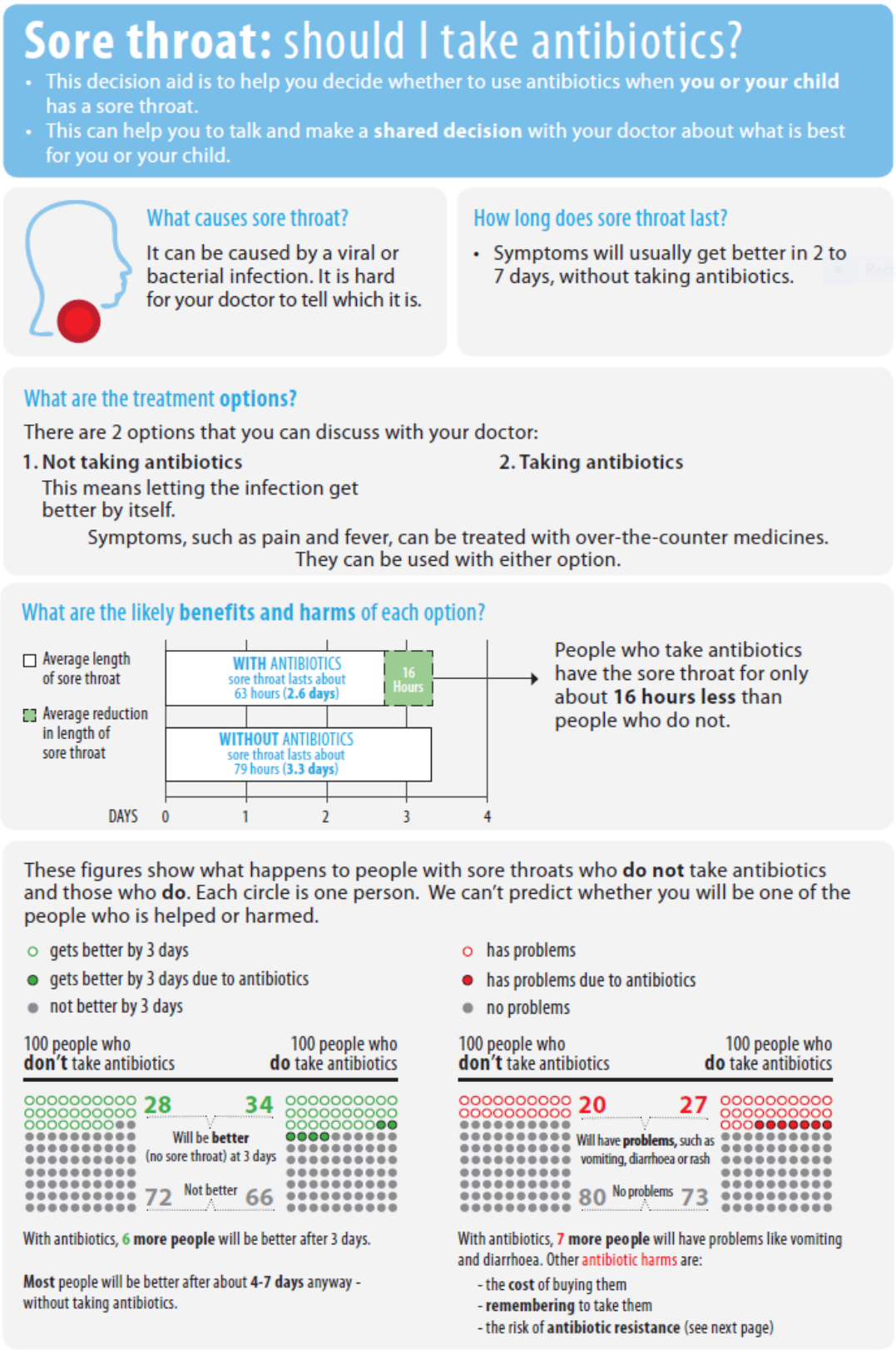


Figure 14: The front side of the two-sided A4-page decision aid for sore throat

Where do these estimates of benefits and harms come from?

- They are from the most-up-to-date medical evidence of benefits and harms about what works best. This is a review of 27 studies, and almost 13,000 people, that looked at antibiotic use in people with sore throat.
- The quality of this research evidence is ranked as high. This means that further research is very unlikely to change these estimates.

Why might antibiotics be used?

There are a few special reasons why your doctor might suggest antibiotics. This might be if the sore throat is caused by a dangerous, but rare, type of bacterium. Or in people who are at a high risk of complications, such as Indigenous people.

What is antibiotic resistance?

- Using antibiotics means the bacteria can develop resistance to the antibiotic.
- This means that **antibiotics will not work if you or your child needs them in the future** to treat a bacterial infection.
- A person who has recently used antibiotics is more likely to have resistant bacteria in their body.

Are there other things I can do?

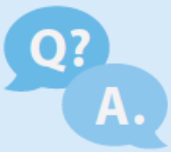
- Pain and fever are best treated with over-the-counter **paracetamol and/or ibuprofen.** Do not give more than the maximum recommended dose. Read the dose information on the packet.
- Aspirin should NOT be used with children who are younger than 16 years.
- Gargle with warm salty water.
- Suck an ice cube or throat lozenge.

When should you see a doctor and get further help?

If the person with the sore throat has any of these signs:

- Very drowsy
- fast, noisy, or difficulty breathing, or shortness of breath
- Cold or discoloured hands and/or feet with a warm body
- Pain in the arms and/or legs
- Unusual skin colour (pale or blue) around the lips
- A rash that does not fade when the skin is pressed

Questions to consider when talking with your doctor



- ☐ Do I need antibiotics?
- ☐ What happens if I don't take antibiotics?
- ☐ Do I know enough about the benefits and harms of:
  - taking antibiotics?
  - not taking antibiotics?
- ☐ Am I clear about which benefits and harms matter most to me?
- ☐ Do I have enough information and support to decide?

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Last reviewed: November 2015. Update due: November 2017. Developed by Peter Coxeter, Professor Chris Del Mar and Professor Tammy Hoffmann - Centre for Research in Evidence-Based Practice, Bond University. Decision Aid development funded by the National Health and Medical Research Council (APP1044904).

Figure 2 (continued): The back side of the two-sided A4-page decision aid for sore throat

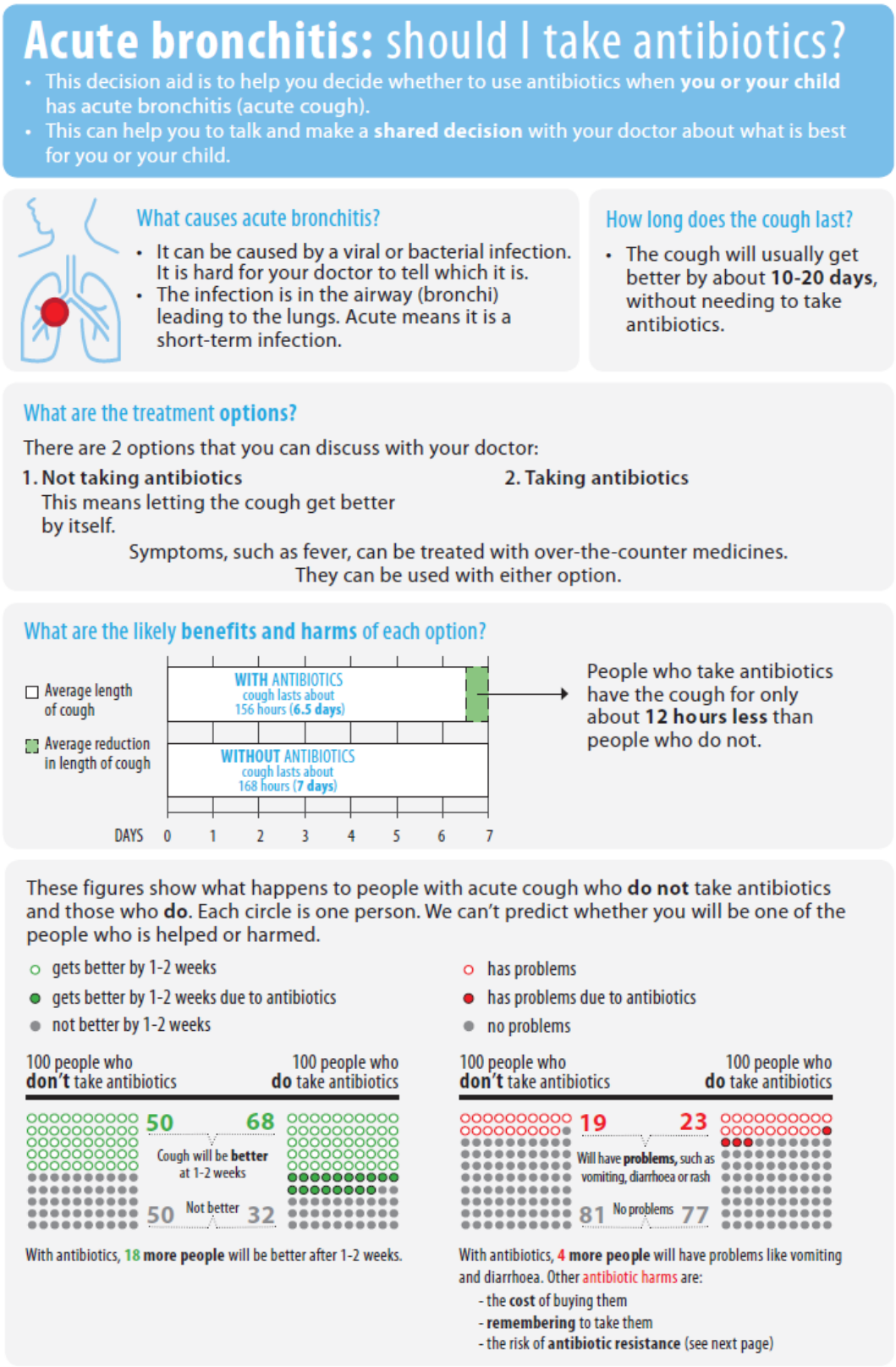


Figure 15: The front side of the two-sided A4-page decision aid for acute bronchitis

Where do these estimates of benefits and harms come from?

- They come from the most-up-to-date medical evidence of benefits and harms about what works best. This is a review of 17 studies, and over 5000 people, that looked at antibiotic use in people with acute bronchitis.
- The quality of this research evidence is ranked as high. This means that further research is very unlikely to change these estimates.

Why might antibiotics be used?

If the infection is in the lung, it is called pneumonia. This is unlikely. However if it is pneumonia, it can be more serious. Your doctor may talk with you about why antibiotics might be needed. Coughing up coloured phlegm (spit) is not a sign that antibiotics are needed.

What is antibiotic resistance?

- Using antibiotics means the bacteria can develop resistance to the antibiotic.
- This means that **antibiotics will not work if you or your child needs them in the future** to treat a bacterial infection.
- A person who has recently used antibiotics is more likely to have resistant bacteria in their body.

Are there other things I can do?

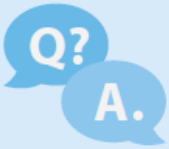
- Fever is best treated with over-the-counter **paracetamol and/or ibuprofen**. Do not give more than the maximum recommended dose. Read the dose information on the packet.
- Aspirin should NOT be used with children who are younger than 16 years.
- Some people find that taking **honey** helps to settle the cough. Take 1-2 teaspoons, just before bedtime. The honey can be given in a drink such as warm water. Honey should not be given to children less than 12 months old.

When should you see a doctor and get further help?

If the person with the cough has any of these signs:

- Very drowsy
- Fast or difficulty breathing, wheezing, or shortness of breath
- Cold or discoloured hands and/or feet with a warm body
- Pain in the arms and/or legs
- Coughing blood
- Unusual skin colour (pale or blue) around the lips
- A rash that does not fade when the skin is pressed

Questions to consider when talking with your doctor



- ☐ Do I need antibiotics?
- ☐ What happens if I don't take antibiotics?
- ☐ Do I know enough about the benefits and harms of:
  - taking antibiotics?
  - not taking antibiotics?
- ☐ Am I clear about which benefits and harms matter most to me?
- ☐ Do I have enough information and support to decide?

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Last reviewed: November 2015. Update due: November 2017. Developed by Peter Coxeter, Professor Chris Del Mar and Professor Tammy Hoffmann - Centre for Research in Evidence-Based Practice, Bond University. Decision Aid development funded by the National Health and Medical Research Council (APP1044904).

Figure 15 (continued): The back side of the two-sided A4-page decision aid for acute bronchitis

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Chapter 7

Preparing Parents to Make an Informed Choice About Antibiotic Use for Common Acute Respiratory Infections in Children: A Randomised Trial of Brief Decision Aids in a Hypothetical Scenario

Peter Coxeter, Chris Del Mar, Tammy Hoffmann.

The Patient: Patient-Centered Outcomes Research. 2017; 10(4):463-474.

Impact Factor: 2.674

Preamble to Chapter 7

Chapter 7 consists of Study 3 which is published as a paper titled *"Preparing parents to make an informed choice about antibiotic use for common acute respiratory infections in children: a randomised trial of brief decision aids in a hypothetical scenario"*, published in The Patient – Patient-Centered Outcomes Research, February 2017. It describes the randomised trial evaluation of the decision aids that were described in Chapter 6.

Work arising from this chapter was accepted for oral presentation at the Gold Coast Health and Medical Research Conference in 2016.

Abstract

Background

Childhood ARIs are one of the most common reasons for primary care consultations and for receiving an antibiotic. Public awareness of antibiotic benefit and harms for these conditions is low. To facilitate informed decision making, ideally in collaboration with their doctor, parents need clear communication about benefits and harms. Decision aids may be able to facilitate this process.

Objective

The aim of this study was to evaluate the effectiveness of three decision aids about antibiotic use for common ARIs in children.

Methods

Adult parents of children aged 1–16 years (n = 120) were recruited from community settings and then randomised using a computer-generated randomisation sequence to receive a decision aid (n = 60) or fact sheet (n = 60). Allocation was concealed and used sealed and opaque sequentially numbered envelopes. Participants self-completed questionnaires at baseline and immediately post-intervention. The primary outcome was informed choice (conceptual and numerical knowledge; attitudes towards, and intention to use, antibiotics for a future ARI). Secondary outcomes were decisional conflict, decisional self-efficacy, and material acceptability.

Results

After reading the information, significantly more intervention group participants made an informed choice [57%] compared with control group participants [29%] [difference 28, 5% confidence interval (CI) 11–45%, $p<0.01$], and had higher total knowledge [mean difference (MD) 2.8, 95% CI 2.2–3.5, $p<0.01$], conceptual knowledge (MD 0.7, 95% CI 0.4–1.1, $p<0.01$) and numerical knowledge (MD 2.1, 95% CI 1.6–2.5, $p<0.01$). Between-group differences in

attitudes or intention to use antibiotics were not significant. Most intervention group participants found the information understandable and liked the aids' format and features.

Conclusion

The decision aids prepared parents to make an informed choice about antibiotic use more than fact sheets, in a hypothetical situation. Their effect within a consultation needs to be evaluated.

Key Points for Decision Makers

There is a trade-off between antibiotic benefits and harms for acute respiratory infections (ARIs) in children. To make informed decisions, parents need to understand these trade-offs.

Decision aids can be used to help communicate evidence about antibiotic benefits and harms.

In this randomised trial, decision aids improved parents' knowledge and informed choice about antibiotic use for ARIs in a hypothetical situation. Effects of the decision aids in a consultation should be evaluated next.

Introduction

Acute respiratory infections (ARIs) in children are one of the most common reasons for primary care consultations.[1-5] Antibiotic prescribing rates for common childhood ARIs remain excessive,[3-6] even after the dissemination of evidence that antibiotics typically have minimal benefit in reducing symptoms or complications,[7-9] and that small benefits may be outweighed by harms. These include common and relatively minor harms, such as diarrhoea,[10] but also the risk of contributing to antibiotic resistance.[11] Antibiotic resistance, now a global public health crisis, is directly caused by antibiotic use.[12] Reducing antibiotic use for ARIs in primary care is a priority because this use is the most common and least necessary of uses of antibiotics.[12,13] Several factors influence whether antibiotics are prescribed in this setting. Children are

perceived by doctors and parents to be more vulnerable than adults to the risk of harm from ARIs.[14] Diagnostic uncertainty is coupled with concern that the disease might progress, and many doctors perceive that patients/parents expect an antibiotic.[15] Patients generally overestimate the benefits of treatments and underestimate their harms.[16] This also applies to beliefs about antibiotics, with many parents overestimating antibiotic benefits and underestimating their harms.[17,18] This can be a contributor to some patients believing that antibiotics are a necessary treatment for ARIs and explicitly requesting them.[19] Antibiotic prescribing reinforces expectations of antibiotics for future ARIs.[20,21]

The counterpoise between antibiotic benefits and harms suggests a need for preference-sensitive care. Shared decision making is a way to provide this,[22] with its focus on communication and evidence-based practice skills, and steps that include eliciting patients' expectations and preferences, clarifying misperceptions, and discussing evidence for the benefits and harms of each option.[23] Patient decision aids are one of several types of tools that can be used to support shared decision making. They can improve patients' knowledge about treatment options, accuracy of perceptions about the benefits and harms of each option, active participation in decision making, and clinician–patient communication.[24]

In a Cochrane review,[25] we recently showed that interventions that aimed to facilitate shared decision making significantly reduced antibiotic prescribing for ARIs in primary care in the short-term, without an increase in re-consultations for the same illness episode or a decrease in patient satisfaction; however, the scope, extensive training requirements, and accessibility of most of these interventions are prohibitive to widespread and sustainable implementation. Some studies used written patient materials as a component of multifaceted interventions, but only two studies (one pilot,[26] one main trial [27]) incorporated the use of a decision aid. The decision aid combined all ARIs into a single aid, was predominately aimed at clinicians (as it included diagnostic probabilities to assist with managing clinical uncertainty), and its acceptability to patients has not been evaluated. Further analysis of the main trial found no significant intervention effect on patients' intention to engage in shared decision making for antibiotic use in future occurrences of ARIs, and concluded that patient-targeted interventions may be necessary to achieve this aim.[28]

Despite the prevalence of antibiotic prescribing for common childhood ARIs in primary care, as well as the need for parents to be adequately informed prior to making preference-sensitive decisions in collaboration with their doctor about antibiotic use, there is a lack of existing brief decision support tools whose acceptability has been evaluated with parents. With the eventual goal of facilitating shared decision making about antibiotic use in ARI

consultations, we developed three brief decision aids for parents relating to acute otitis media sore throat, and acute bronchitis in children. This study is one stage of a multi-stage evaluation, as is recommended in the development of decision aids.[29] The aim of the present study was to evaluate the ability of the decision aids to help parents make an informed choice in a hypothetical scenario, and parents' perceptions of the usefulness and acceptability of the decision aids.

Methods

Study Design

This was a two-arm, parallel group, randomised trial.

Participants

A convenience sample of eligible parents was recruited between September and December 2015 from several community locations, such as playgroups in South-East Queensland, Australia. Adult (≥18 years) parents or primary caregivers of children aged 1–16 years (inclusive) were invited to participate. Children were not required to be experiencing an ARI at that time for parents to be eligible to participate. Eligible parents who were interested in participating were provided with a participant information sheet prior to being invited to provide voluntary written consent. The trial was approved by the Bond University Human Research Ethics Committee and was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12615000843550).

Randomisation and Blinding

Eligible participants were randomly assigned to one of two information formats: one of the new decision aids (intervention) or a fact sheet (control), for one of three common childhood ARIs (acute otitis media, sore throat, and acute bronchitis). The randomisation sequence was computer generated (www.randomization.com) by a researcher independent of the project team, who placed and sealed the allocated information format and corresponding pre- and post-questionnaire into sequentially numbered opaque envelopes. Group allocation was concealed to both participants and interviewers until written consent had been obtained.

Procedure

The consenting parent and study researcher signed and dated a consent form attached to the envelope. The researcher opened the envelope and asked the participant to self-complete the pre-test questionnaire to assess baseline knowledge and attitudes about antibiotic use for the ARI covered in the information allocated to them, and the intention of using antibiotics when their child had a similar future illness. The researcher returned the completed questionnaire to the envelope, and then provided the participant with either the intervention or control information (for one of the three infections) that they had been randomised to. Participants could read the information at their own pace. The researcher unobtrusively recorded the time this took. After returning the intervention or control information to the envelope, the participant immediately completed the post-test questionnaire. This contained antibiotic knowledge, attitude, and intention questions identical to those in the baseline questionnaire, as well as questions about confidence in making a decision and any discomfort with the decision reached. A copy of the pre- and post-questions for acute otitis media is provided as an example in Appendix 1. The interaction between the researcher and participant was standardised, and the written materials were provided to both groups in a neutral manner and with minimal interaction beyond conveying procedural instructions. Researchers did not provide participants with any additional information, or counsel them about ARIs or antibiotic use.

Intervention

The patient decision aids were systematically developed in accord with the updated review of the International Patient Decision Aids Standards (IPDAS) international quality criteria and development processes.[29] The content of each decision aid was informed by (i) findings from systematic reviews [15,30] and observational studies [14,17,18,31-33] exploring patients' and parents' beliefs about, and expectations of, antibiotics for ARIs; (ii) the relevant Cochrane systematic reviews (acute otitis media,[9] acute bronchitis,[7] sore throat [8]), and a meta-analysis of antibiotic harms [10] for quantification of antibiotic benefits and harms; and (iii) risk communication research about optimal methods for numerical, graphical and narrative presentation of benefit and harm data.[34,35] The decision aids were evaluated for face and content validity with an advisory group of clinicians and researchers with clinical and research expertise in general practice, ARIs, infectious diseases, evidence-based practice and shared decision making. The decision aids were developed iteratively, and were reviewed and revised during pilot testing with a purposeful sample of eligible parents (n = 12) and general practitioners (n = 6). Figure 1 shows the front page of the two-page A4 decision aid for acute otitis media.

Control

The fact sheets provided to the control group contained information currently available, for each ARI, to the Australian public from NPS MedicineWise, an independent, not-for-profit organisation who, as part of their activities, provide health information resources. Their website contained a downloadable fact sheet for acute otitis media and antibiotics in children.[36] For sore throat [37] and acute bronchitis,[38] the consumer information on the website was not formatted for easy download or printing, therefore we converted it into a format that matched the acute otitis media fact sheet.

Outcomes

Our primary outcome was a composite measure of informed choice. This is based on the multidimensional model of informed choice.[39] which has been previously used in trials of decision aids,[40,41] and contains constructs of decision quality that are often used when evaluating decision aids.[42] It consists of three constructs: knowledge, attitudes, and intentions. A participant's choice was considered to be informed if his/her level of knowledge was adequate, and their attitudes and intention consistent [40] (i.e. positive attitude to antibiotic use and high intention to use; or negative attitude to antibiotic use and low intention to use). There were ten knowledge questions (see Table 8 - five assessing conceptual knowledge questions about antibiotic use for the relevant ARI (true/false), and five assessing numerical knowledge about the quantitative benefits and harms of antibiotic use (open-ended responses). A score of ≥50% (with at least two correct numerical items) was set as the threshold for adequate knowledge.[43] Attitude to antibiotic use was measured using a validated 6-item scale,[40,41,44] with five response options ('strongly disagree' to 'strongly agree'), forming a scale from 6 to 30. The threshold for a positive attitude (to antibiotic use) was set at 24, based on previous work.[40] A single question with five response options ('definitely will not' to 'definitely will') was used to assess the intention to use an antibiotic for a child's ARI in the future. Secondary outcomes were decisional conflict (10-item low-literacy decisional conflict scale);[45] self-efficacy in decision making (four items from the decision self-efficacy scale);[46] and usability and acceptability of the decision aids.[40]

Sample Size Calculation

Using an alpha of 0.05 and 90% power to detect a difference of 30% (based on data from previous studies [47,48]) in the proportion of people who made an informed choice, we

estimated a minimum of 104 people would be required. This was rounded to 108 to enable equal group sizes.

Statistical Analysis

Quantitative data were entered into Stata version 13 (StataCorp LP, College Station, TX, USA). Responses to numerical knowledge questions were considered correct if a participant's answer was within ±10 of the actual estimate. For example, in the acute otitis media question about the number of children out of 100 who will get better without antibiotics, in which the answer was 84, any response in the range of 74–94 was marked as correct. When analysing responses to the intention question, the 'likely to' and 'definitely will' response categories were collapsed to indicate a positive intention, and 'definitely will not' and 'not likely to' were collapsed to indicate a negative intention.

The primary analysis was a comparison of the proportion of participants in the intervention and control groups who were making an informed choice. Continuous outcomes were analysed using independent sample t tests, and categorical and binary outcomes were analysed using Chi square tests. Adjustment for differences between the groups in the baseline intention-to-use measure was performed using ordinal logistic regression for the between-group analysis for post-intervention responses to this question. Data from open-ended questions about the acceptability of the aids were categorised independently by two authors for thematic analysis.

Results

During the recruitment phase (September–December 2015), 141 eligible participants were invited to participate, 120 were recruited and none were lost to follow-up (Figure 16). Most participants were Australian-born, female, between 36 and 45 years of age, married or living with a partner, had completed tertiary education, and were employed full-time. Baseline characteristics for the two groups were similar for all characteristics except education, in which a higher proportion of participants in the intervention group had a higher level of educational attainment (Table 7).

Although the groups did not differ on baseline knowledge scores (conceptual, numerical or combined) (Table 8), we conducted a post hoc analysis using logistic regression to adjust for level of educational attainment, and found it was not statistically significant and did not lead to any substantial change in the primary outcome.

Baseline knowledge level was moderate in both groups (Table 8). The intervention group's mean conceptual knowledge score (maximum possible score of 5) was 3.0, while the control group's score was 3.1. Numerical knowledge scores (out of 5) were lower, with a mean of 1.5 in both groups. Baseline attitude towards antibiotic use was positive in 18% of participants in the intervention group and 19% of participants in the control group, while a greater proportion of intervention group participants (42%) had a positive intention to future antibiotic use than in the control group (32%). At baseline, the proportion of participants who made an informed choice about antibiotic use was low and similar between the intervention (15%) and control (18%) groups.

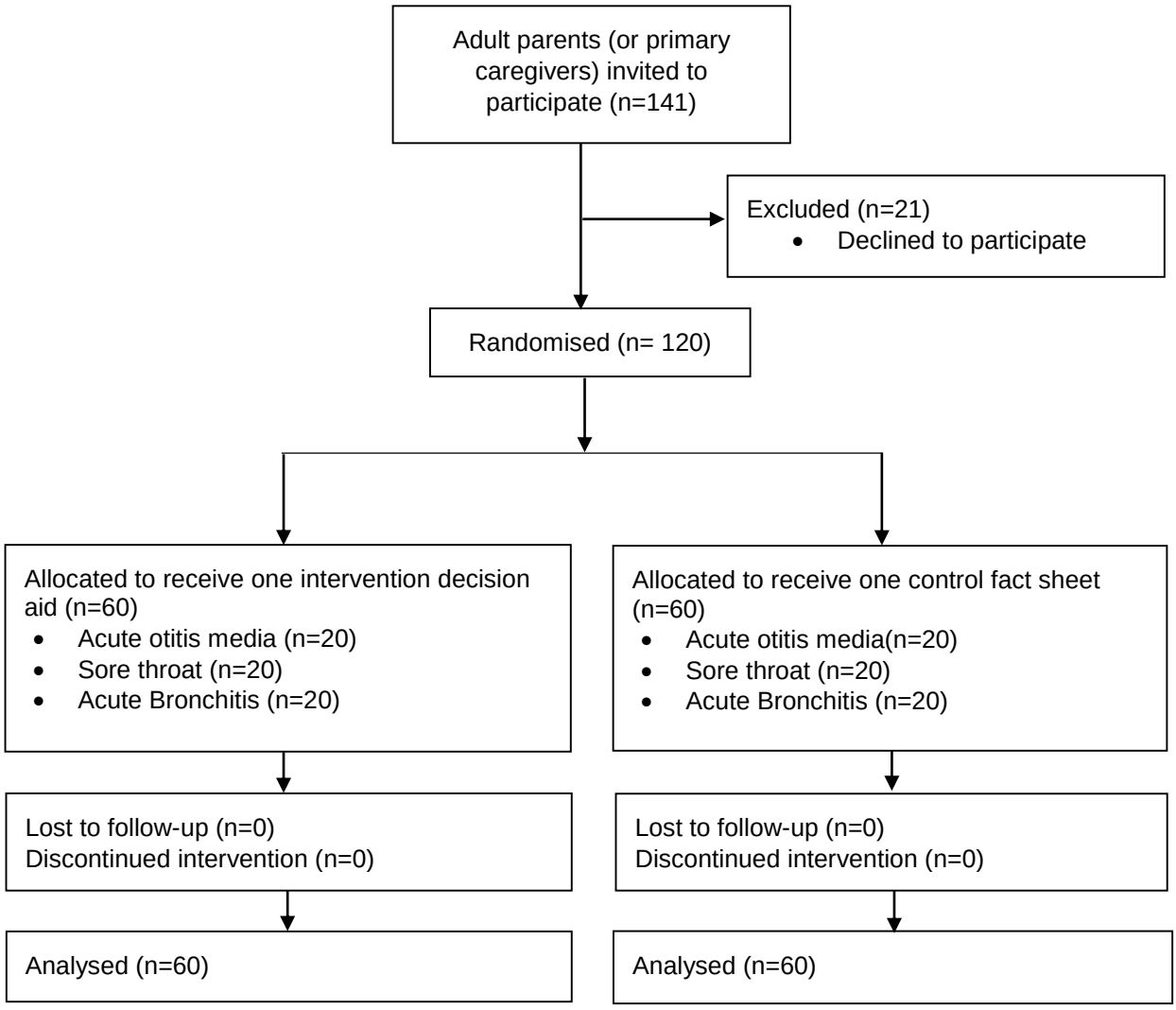

Figure 16: Flow of participants through the trial

Table 7: Baseline characteristics of participants (N=120)

	Intervention group ($n = 60$)	Control group ($n = 60$)
Gender		
Female	43 (73)	45 (78)
Age, years		
18–25	0 (0)	1 (2)
26–35	18 (31)	20 (35)
36–45	32 (54)	30 (52)
46–55	9 (15)	4 (7)
≥56	0 (0)	3 (5)
Country of birth		
Australia	45 (76)	45 (78)
Other	14 (24)	13 (22)
Main language spoken at home		
English	57 (97)	56 (97)
Other	2 (3)	2 (3)
Marital status		
Married or living with a partner	54 (90)	58 (98)
Single adult with primary caregiving responsibility	5 (8)	1 (2)
Other	1 (2)	0 (0)
Highest level of education		
Junior high school	1 (2)	1 (2)
Senior high school	0 (0)	7 (12)
Trade certificate or apprenticeship	0 (0)	2 (3)
Graduate diploma or certificate	16 (27)	11 (19)
Undergraduate degree	25 (42)	22 (37)
Postgraduate student	18 (30)	16 (27)
Employment		
Full-time (≥30 h per week)	34 (57)	31 (53)
Part-time (<30 h per week)	12 (20)	16 (27)
Casually employed	6 (10)	2 (3)
Not currently in paid employment	8 (13)	10 (17)

Data are expressed as n (%). Responses to some questions had missing data for one to three participants

After the materials had been read, more participants in the intervention group [28% more, 95% confidence interval (CI) 11–45%, $p < 0.01$] than in the control group made an informed choice about antibiotic use for a child's future ARI. Individual constructs of this composite outcome also reflect this (Table 8). Intervention group participants also had higher scores for total knowledge [mean difference (MD) 2.8, 95% CI 2.2–3.5, $p < 0.01$], conceptual knowledge (MD 0.7, 95% CI 0.4–1.1, $p < 0.01$) and numerical knowledge (MD 2.1, 95% CI 1.6–2.5, $p < 0.01$). More participants in the intervention group had adequate knowledge than in the control group (48% more, 95% CI 33–63%; $p < 0.01$).

At post-intervention, there were no significant differences between the number of participants in each group who had a positive attitude towards antibiotic use. After adjustment for the baseline difference between groups in the proportion of participants with a positive intention to antibiotic use, the intervention group participants were more likely to have a positive intention than those in the control group, but the difference was not statistically significant (odds ratio 0.43, 95% CI 0.18–1.09, $p = 0.08$). Decisional conflict scores were low, and self-efficacy for making the decision was high, in both groups, with no significant between-group differences (Table 8).

Table 8: Baseline and post-intervention outcomes for the intervention and control groups

	Baseline		Post-intervention		Difference (95% CI)	*p* value
	Intervention group	Control group	Intervention group	Control group		
Informed choice[a] [*n* (%)]						
Would make an informed choice	9 (15)	11 (18)	34 (57)	17 (29)	28 (11–45)	<0.01
Conceptual knowledge [*n* (%) correct]						
Antibiotics are needed for viral infection	46 (77)	50 (83)	55 (92)	54 (92)	0.2 (−10 to 10)	0.97
Antibiotics reduce symptom duration	40 (68)	45 (75)	48 (81)	53 (91)	−10 (−22 to 2)	0.12
People do not usually need to take antibiotics	35 (60)	36 (60)	57 (95)	55 (93)	2 (−7 to 10)	0.67
If a person takes an antibiotic, the antibiotic might not work for a serious infection another time	35 (58)	27 (45)	58 (97)	37 (63)	34 (21–47)	<0.01
Doctors can predict if your child will benefit from taking antibiotics	26 (43)	27 (45)	48 (81)	20 (34)	48 (32–63)	<0.01
Total conceptual knowledge score [mean (SD)]	3.0 (1.3)	3.1 (1.1)	4.4 (0.8)	3.7 (1.1)	0.7 (0.4–1.1)	<0.01
Numerical knowledge [*n* (%) correct]						
Average duration of illness	48 (81)	46 (79)	55 (92)	53 (90)	2 (−9 to 12)	0.72
Number out of 100 better without an antibiotic	5 (9)	7 (13)	45 (76)	7 (14)	63 (46–77)	<0.01
Number out of 100 better with an antibiotic	11 (20)	10 (18)	44 (75)	10 (19)	55 (40–71)	<0.01
Number out of 100 with side effects from an antibiotic	8 (15)	11 (19)	42 (71)	16 (30)	42 (25–58)	<0.01
Number out of 100 with side effects without an antibiotic	16 (30)	13 (23)	39 (67)	13 (24)	44 (27–60)	<0.01
Total numerical knowledge score [mean (SD)]	1.5 (0.8)	1.5 (0.9)	3.8 (1.5)	1.7 (1.0)	2.1 (1.6–2.5)	<0.01
Total knowledge score [mean (SD)][b]	4.5 (1.5)	4.5 (1.4)	8.2 (1.7)	5.4 (1.3)	2.8 (2.2–3.4)	<0.01
'Adequate' knowledge [*n* (%)][c]	19 (32)	18 (30)	52 (87)	23 (39)	48 (33–63)	<0.01
Positive attitude to antibiotic use (score ≥24)[d] [*n* (%)]	11 (18)	11 (19)	7 (12)	2 (3)	8 (−1 to 18)	0.09
Decisional conflict score[e] [mean (SD)]	–	–	8.0 (14.5)	11.0 (16.6)	−3.0 (−8.7 to 2.7)	0.29
Decision self-efficacy score[f] [mean (SD)]	–	–	86.4 (16.1)	84.1 (17.3)	2.2 (−3.8 to 8.3)	0.47

SD Standard deviation, *CI* confidence interval

[a] Informed choice was defined as an adequate level of knowledge, and consistent attitudes and intention (i.e. positive attitude to antibiotic use and intention to use; or negative attitude to antibiotic use and no intention to use)

[b] Knowledge scale of 0–10 contained conceptual and numerical items

[c] Adequate knowledge defined as five or more correct items, including two or more numerical items

[d] Attitude items were rated on a scale from strongly disagree (1) to strongly agree (5), and items included *'Taking antibiotics is beneficial'*, *'Taking antibiotics is harmful'* (reverse scored), *'Taking antibiotics is a good thing'*, *'Taking antibiotics is a bad thing'* (reverse scored), *'Taking antibiotics is important'*, and *'Taking antibiotics is worthwhile'*. Total scores could range from 6 to 30, with higher scores indicating a more positive attitude to antibiotic use

[e] Decisional conflict scores can range from 0 (no decisional conflict) to 100 (extremely high decisional conflict)

[f] Decision self-efficacy scores can range from 0 (extremely low self-efficacy) to 100 (extremely high self-efficacy)

Table 9 summarises participants' views about the intervention and control materials. The majority of participants thought the length of materials was just right, although significantly more in the intervention group (90%) compared with the control group (60%) [95% CI 15–45%, $p < 0.01$]. The time in minutes taken to read the information was similar in both groups, with a mean (SD) of 4.3 (1.4) in the intervention group and 4.7 (2.2) in the control group. There were no significant differences between the groups in the proportion of participants who thought the information was new, clear and easy to understand, and helpful in deciding about antibiotic use for a child's illness. Significantly more participants who received a decision aid (95%) than control information (76%) agreed or strongly agreed they would recommend the information to other parents deciding about antibiotic use for a child with an ARI (19% difference, 95% CI 7–31%, $p < 0.01$).

More participants who received decision aids provided a response to the open question ''What did you like about the information sheet?''. Frequent responses included the format, structure and content; that the information was concise, clear, and easy to read and/or understand; and the graphical representation of benefits and harms numerical information. A few participants (n = 5) also indicated that they liked the neutral presentation of information. In response to the question ''How could the decision aids be improved?'' a few suggestions included adding information on viral versus bacterial aetiology (n = 1), the role of antibiotics in preventing complications (n = 1), types of antibiotics (n = 1), and other treatment options (n= 2).

Table 9: Participants' responses about the suitability of the information materials:

	Intervention group n(%)	Control group n(%)	Difference (95% CI)	*p*-value
Length of information sheet				
Too long	6 (10)	19 (33)	−23 (−37 to −0.1)	<0.01
Just right	53 (90)	35 (60)	30 (15–45)	<0.01
Too short	0 (0)	4 (7)	−7 (−14 to −0.0)	0.04
Information was new				
None	0 (0.0)	2 (3)	−3.4 (−8 to 1)	0.15
Some of it	43 (73)	46 (79)	−6.4 (−22 to 9)	0.42
Most of it	14 (24)	7 (12)	12 (−2 to 25)	0.10
All of it	2 (3)	3 (5)	−2 (−9 to 6)	0.63
Information was clear and easy to understand				
Strongly disagree or disagree	2 (3)	3 (5)	−2 (−9 to 5)	0.58
Neither agree nor disagree	3 (5)	4 (7)	−2 (−11 to 7)	0.65
Agree or strongly agree	54 (92)	51 (88)	4 (−7 to 15)	0.47
Information was helpful in making a decision about antibiotic use for a child				
Strongly disagree or disagree	2 (3)	6 (10)	−7 (−16 to 2)	0.12
Neither agree nor disagree	10 (17)	10 (17)	0 (−14 to 14)	1.00
Agree or strongly agree	47 (80)	42 (72)	8 (−7 to 23)	0.47
Would recommend this information to other parents				
Strongly disagree or disagree	1 (2)	6 (10)	−8 (−17 to 1)	0.07
Neither agree or disagree	2 (3)	8 (14)	−11 (−21 to 1)	0.03
Agree or strongly agree	56 (95)	44 (76)	19 (7–31)	<0.01

Data are expressed as *n* (%). Responses to some questions had missing data for one to three participants
CI confidence interval

Discussion

We developed and evaluated the effect of decision aids on parents' ability to construct informed preferences and make informed choices about antibiotic use in three common childhood ARIs in the context of a hypothetical decision, as a precursor to evaluating their effect on facilitating shared decision making during a clinical consultation. This trial found that the decision aids enabled more parents to make an informed choice about antibiotic use in this type of hypothetical situation and improved parents' knowledge, but did not alter their attitudes towards antibiotic use or their intention to use antibiotics when their child has an ARI in the future. The findings that the decision aids substantially improved conceptual and numerical knowledge are consistent with systematic review findings on the effects of decision aids on knowledge and risk perception accuracy for other treatment decisions.[24] The substantial improvement in numerical knowledge in the intervention group is not surprising as the information was only provided in the decision aids. The importance of improving this type of knowledge comes from studies showing that patients typically overestimate the benefits and underestimate the harms of treatments,[16] including for antibiotics in ARIs.[17,18] These overly optimistic expectations contribute to unnecessary treatment.[16] Shared decision making provides the opportunity to redress this,[23] with clinicians and patients able to discuss the likelihood of benefit and harm, and the trade-off between the two. It is unclear to what extent individuals, when deciding about antibiotic use, weigh more proximal individual perceptions about antibiotic benefit and harm, against the more distal individual or community consequences of antibiotic resistance (the 'tragedy of the commons' [49]). Measurement of parents' risk perceptions about the benefits and harms of antibiotics is another contribution of this study to the literature. As far as we are aware,[16] no other studies have quantified people's expectations about antibiotic benefits and harms, and for their use in any condition. Our baseline knowledge scores provide this information and reveal that parents generally have inaccurate risk perceptions about antibiotic benefits and harms. Inaccurately high expectations of antibiotic benefits in ARIs have been reported in primary care paediatricians and have been identified as a driver of inappropriately high prescribing rates;[50] understanding the contribution that patients/parents also bring to the consultation is important when exploring the issues surrounding antibiotic decision making.

After reading the materials, there was reduction in the proportion of parents who had a positive attitude to antibiotic use in both groups, although the difference between the groups was not significant. The intervention and control materials took different approaches to trying

to influence parents' attitudes about antibiotics; the fact sheets explicitly stated that antibiotics were unnecessary and the decision aids presented the benefits and harms in a balanced manner (which is a criterion for the presentation of information in a decision aid [51]). The proportion of parents who intended to use antibiotics in the future also decreased in both groups but did not differ between the groups. As decisions about antibiotic use typically occur in the context of a consultation with a doctor, it is not possible to know from this study, which used a hypothetical situation, what effect the decision aids may have on parents' attitudes and actual antibiotic use when their child is ill. It may be that both authoritatively presented information, which directs parents not to take antibiotics, and information that presents the benefits and harms, and encourages parents to be involved in making the decision, may alter attitudes and behaviour. However, when it comes to health decisions, the majority of participants prefer to be involved in decision making.[52-54] For decisions about antibiotics for children, most parents (75%) prefer to participate in making this decision with their doctor.[17]

The findings that decisional conflict was low in both groups and below the threshold (of 25) associated with an ability to implement decisions,[45] and that decisional self-efficacy was high in both groups, also need to be interpreted cautiously. These scores might not reflect the actual decisional self-efficacy and decisional conflict that occurs when parents have a child ill with an ARI and have consulted a doctor about their child's care. However, low decisional conflict may also reflect that ARIs are familiar to parents, occur frequently, are not perceived as serious, and hence the decision making associated with them is not likely to produce high levels of decisional conflict. In a review of decisional conflict in shared decision-making situations in Canadian primary care (including decision making about antibiotics for ARIs), a 'clinically significant' level of decisional conflict was found in a low proportion (10–31%) of encounters.[55]

Development of the decision aids followed the recommended phased approach,[29] and during development they were iteratively tested with patients and general practitioners, with feedback about the layout and wording incorporated into the version tested in the current study. Acceptability and usefulness of the decision aids was confirmed in this study, with most intervention group participants reporting them to be easy to read and understand, useful, and liking the length and visual presentation of probability data. Evaluation of the decision aids when they are used in a consultation with general practitioners and their effect on antibiotic use, as well as the quality of the decision making during consultations, will be the next phase. Whether using decision aids will alter antibiotic prescribing rates is unclear.

Strengths of our trial include the systematic development of the decision aids, randomised design, and no loss to follow-up. We pre-specified a conservative threshold for the type of knowledge required to make an informed choice, using conceptual and numerical measurement, underpinned by a theoretical framework.[43] We also directly compared decision aids with consumer information of high standard (considerably greater than is routinely provided in primary care in Australia), which may have underestimated the effectiveness of the decision aids when used within a clinical context.

Limitations in the generalisability of results stem from asking parents about a hypothetical illness situation. Although this is somewhat mitigated by the high prevalence of ARIs during childhood [56] (ARIs are the most frequent reason for children to be seen by a primary care doctor), so few parents in this study will have not experienced their child having had at least one of these illnesses at least once. Nevertheless, the hypothetical scenario may have influenced measurement of some constructs of the composite informed choice endpoint, although this outcome has been used in other trials of decision aids in which participants were not necessarily needing to make a decision at the time of receiving a decision aid but perhaps at some point in the future (such as cancer screening decisions).[40,57,58] Knowledge and risk perception is unlikely to be affected by the hypothetical scenario, whereas parents' attitudes toward antibiotic use, intent to use an antibiotic, and level of decisional conflict might differ when their child is sick and there is a need to make and act on a decision. These constructs might also be influenced by the interaction with a doctor in a consultation (where the decision aids are ultimately intended for use). Parents' judgement of the usability and acceptability of the materials is unlikely to be affected by the hypothetical setting. The high educational attainment of the participants in both study groups may limit generalisability. A further limitation is that recall accuracy (particularly of risk probability questions) may have been aided by administration of the post-test questionnaire immediately after reading the allocated information, although this would not be particularly different from how the aids would be used during primary care consultations, and is a common approach in trials of decision aids.[24]

Conclusions

Brief decision aids about antibiotic use for common ARIs in children enabled more parents to make an informed choice about this decision in a hypothetical situation. However, substantial improvements in knowledge about the benefits and harms of antibiotics may not be

sufficient to change parents' attitudes about antibiotics or their intention to use them for a child with an ARI. Parents liked the format and structure of the decision aids, balanced content, and visual presentation of benefit and harm data. Evaluation of the effectiveness of the decision aids on antibiotic prescribing in primary care is required. Decision aids are intended for use as a tool to facilitate shared decision making between the doctor and patient during a clinical encounter, and their effectiveness in this clinical context needs to be established next.

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Authors' contributions

All authors contributed to the study design and data interpretation. Tammy Hoffman conceptualised the decision aids, and Peter Coxeter, Tammy Hoffman and Chris Del Mar developed the decision aids and designed the trial protocol. Peter Coxeter led the administration of the trial and statistical analysis, and wrote the first draft of the article. All authors contributed to subsequent drafts and the final version.

Compliance with Ethical Standards

This study was approved by the Bond University Human Research Ethics Committee and was conducted in accordance with the ethical standards of the Declaration of Helsinki. Informed consent was obtained from all participants prior to study enrolment.

Conflict of interest

Peter Coxeter, Chris Del Mar and Tammy Hoffman declare no competing interests.

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Appendices

Appendix A: Example pre- and post-questionnaire for acute otitis media (questionnaires for each other ARI were identical except for the indication)

STEP 1

Middle Ear Infection

Interviewer use only
ID:
Time to view sheet:

Please complete these questions BEFORE reading the written information

1. Antibiotics are needed to help children who have *middle ear infection* because it is a viral infection.
    a. True
    b. False

2. Antibiotics reduce how long your child has the symptoms of *middle ear infection* by 3 days.
    a. True
    b. False

3. Children with *middle ear infection* usually don't need to take antibiotics.
    a. True
    b. False

4. If your child uses antibiotics for *middle ear infection*, antibiotics might not work for them if they get a serious infection another time.
    a. True
    b. False

5. Doctors can predict if your child will benefit from taking antibiotics for *middle ear infection.*
    a. True
    b. False

6. How many days do you think that *middle ear infection* usually lasts for, on average?
    _____

7. Of 100 children with *middle ear infection* who **do not** take antibiotics, about how many will be **better** after 2-3 days? _____

8. Of 100 children with *middle ear infection* who **do** take antibiotics, about how many will be **better** after 2-3 days? _____

9. Of 100 children with *middle ear infection* who **do** take antibiotics, about how many will have **side effects** (such as diarrhoea, vomiting, or a rash)? _____

10. Of 100 children with *middle ear infection* who **do not** take antibiotics, about how many will have **side effects** (such as diarrhoea, vomiting, or a rash)? _____

For each of the following questions, **please circle the number from 1 to 5** on the scale that best describes how you feel at the moment.

11. For my child, taking antibiotics for *middle ear infection* is **beneficial**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

12. For my child, taking antibiotics for *middle ear infection* is **harmful**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

13. For my child, taking antibiotics for *middle ear infection* is **a good thing**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

14. For my child, taking antibiotics for *middle ear infection* is **a bad thing**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

15. For my child, taking antibiotics for *middle ear infection* is **important**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

16. For my child, taking antibiotics for *middle ear infection* is **worthwhile**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

And the final question asks you to think about the next time that your child has *middle ear infection.*

17. How **likely are you to use antibiotics**? Please circle one.

1	2	3	4	5
Definitely will not	Not likely to	Unsure	Likely to	Definitely will

STEP 3

Please complete these questions AFTER reading the written information

1. Antibiotics are needed to help children who have *middle ear infection* because it is a viral infection.
   a. True
   b. False

2. Antibiotics reduce how long your child has the symptoms of *middle ear infection* by 3 days.
   a. True
   b. False

3. Children with *middle ear infection* usually don't need to take antibiotics.
   a. True
   b. False

4. If your child uses antibiotics for *middle ear infection*, antibiotics might not work for them if they get a serious infection another time.
   a. True
   b. False

5. Doctors can predict if your child will benefit from taking antibiotics for *middle ear infection.*
   a. True
   b. False

6. How many days do you think *middle ear infection* usually lasts for, on average? _____

7. Of 100 children with *middle ear infection* who **do not** take antibiotics, about how many will be **better** after 2-3 days? _____

8. Of 100 children with *middle ear infection* who **do** take antibiotics, about how many will be **better** after 2-3 days? _____

9. Of 100 children with *middle ear infection* who **do** take antibiotics, about how many children will have **side effects** (such as diarrhoea, vomiting, or a rash)? _____

10. Of 100 children with *middle ear infection* who **do not** take antibiotics, about how many children will have **side effects** (such as diarrhoea, vomiting, or a rash)? _____

For the following questions, **please circle the number from 1 to 5** on the scale that best describes how you feel at the moment. Please read the scale for each question.

11. For my child, taking antibiotics for *middle ear infection* is **beneficial**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

12. For my child, taking antibiotics for *middle ear infection* is **harmful**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

13. For my child, taking antibiotics for *middle ear infection* is **a good thing**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

14. For my child, taking antibiotics for *middle ear infection* is **a bad thing**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

15. For my child, taking antibiotics for *middle ear infection* is **important**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

16. For my child, taking antibiotics for *middle ear infection* is **worthwhile**

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

The next 2 questions (17 and 18) ask you to think about the next time that your child has *middle ear infection*.

17. How **likely are you to use antibiotics**? Please circle one.

1	2	3	4	5
Definitely will not	Not likely to	Unsure	Likely to	Definitely will

Which option do you think you might prefer? Please tick one

- ☐ *Using* antibiotics
- ☐ *Not using* antibiotics

18. Considering the option you prefer, please answer the following questions:

	Yes	Unsure	No
a. Do you know which options are available to you?	☐	☐	☐
b. Do you know the benefits of each option?	☐	☐	☐
c. Do you know the risks and side effects of each option?	☐	☐	☐
d. Are you clear about which benefits matter the most to you?	☐	☐	☐
e. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
f. Do you have enough support from others to make a choice?	☐	☐	☐
g. Are you choosing without pressure from others?	☐	☐	☐
h. Do you have enough advice to make a choice?	☐	☐	☐
i. Are you clear about the best choice for you?	☐	☐	☐
j. Do you feel sure about what to choose?	☐	☐	☐

Below are some things involved in making an informed choice. Please show how confident you feel in doing these things by **circling the number from 0 (not at all confident) to 4 (very confident)** for each item listed below.

I feel confident that I can:

19. Understand the information enough to be able to make a choice

0	1	2	3	4
Not at all confident				Very confident

20. Ask questions without feeling dumb

0	1	2	3	4
Not at all confident				Very confident

21. Express my concerns about each choice

0	1	2	3	4
Not at all confident				Very confident

22. Let the doctor know what's best for me and my child

0	1	2	3	4
Not at all confident				Very confident

The next set of questions asks you what you thought about the written information sheet that you just read.

23. The **length** of the information sheet was:

- ☐ Too long
- ☐ Just right
- ☐ Too short

24. Was information in the sheet **new** to you?

- ☐ None of it
- ☐ Some of it
- ☐ Most of it
- ☐ All of it

25. Was the information sheet **clear** and **easy to understand**?

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

26. Did you find the information sheet **helpful in making a decision** about whether to use antibiotics when your child has *middle ear infection*?

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

27. Would you **recommend this information sheet** to other parents who are deciding whether to use antibiotics with their child when they have *middle ear infection*?

1	2	3	4	5
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

28. What did you like about the information sheet?

29. Are there any suggestions for improvement of the information sheet that you have?

Finally, a few questions about you.

30. Are you:

- ☐ Female
- ☐ Male

31. Which age group are you in?

- ☐ 18 – 25 years
- ☐ 26 – 35 years
- ☐ 36 – 45 years
- ☐ 46 – 55 years
- ☐ > 56 years

32. Which country were you born in?

- □ Australia
- □ Other (please specify):

33. What is the main language spoken in your home?

- □ English
- □ Other (please specify)

34. Do you identify as an Aboriginal or Torres Strait Islander?

- □ Yes
- □ No

35. What is your current living situation?

- □ Married or living with partner
- □ The only adult in the household who has caregiving responsibility for my child/ren
- □ Other

36. What is the highest level of education you have completed?

- □ Junior high school (Grade 9 or 10) or less
- □ Senior high school (Grade 12)
- □ Trade certificate or apprenticeship
- □ Graduate diploma or certificate
- □ Bachelor's degree
- □ Postgraduate degree

37. What is your current employment status?

- □ Full-time employed (30 or more hours per week)
- □ Part-time employed (less than 30 hours per week)
- □ Casually employed
- □ Not currently in paid employment

38. What is your postcode? _____

Thank you very much for your time. Your responses have been very helpful to this research.

Appendix B: Example control fact sheet for acute otitis media

Fact Sheet

My child has a middle ear infection: is an antibiotic necessary?

From your health professional

Your doctor has just told you that your child has a middle-ear infection. Here is some information to help you in the next week or so.

What is a middle-ear infection?

Middle-ear infection is an infection in the small space just behind the eardrum that is common in young children. It is also called otitis media and usually causes an earache.

Most children will have at least one middle-ear infection by 3 years of age.

Middle-ear infections are more common in winter and early spring and often follow a simple common cold.

Will antibiotics help right now?

Middle-ear infections can be due to either viruses or bacteria. Most children (60%) recover from the pain of their infection within 24 hours without antibiotics.

Your child's own immune system will be able to get rid of the infection in a few days in most cases.

Research shows that antibiotics do not relieve earache in the first 24 hours of use but may reduce pain lasting for longer than 2 days.

What are the disadvantages of antibiotics?

- Using antibiotics when you don't need them may make them less effective when you really need them.
- Antibiotics can cause unpleasant side effects such as skin rashes, diarrhoea and vomiting.

How can I help my child feel better?

The doctor examined your child and although your child is unwell, no serious illness has been found that needs antibiotics.

Therefore, the doctor has given you advice on how to treat the ear infection and may have asked you to bring your child back if there is no improvement or worsening of symptoms. Your doctor may provide a prescription for an antibiotic at this stage.

Appendix B (continued): Example control fact sheet for acute otitis media

When should I return to the doctor?

- You should take your child back to the doctor if he/she is not recovering in _____ days.
- You should take your child to the doctor if you feel your child's ear infection is getting worse.

Is there anything I should look out for?

Should you find that your child becomes sicker or develops any new or worrying symptoms such as vomiting or fever (a temperature of 38.5°C or higher), swelling or redness behind the ear, contact your doctor.

Sometimes there is a persistent deafness that continues after a middle-ear infection. Your doctor may suggest a return visit to check that your child is hearing normally again.

Helping your child during a middle-ear infection

Pain relief is the best thing for your child. Give

- paracetamol when required or, alternatively, give ibuprofen. Check the package for the correct dose. Do not exceed the specified dose. Contact your doctor if symptoms don't improve after 48 hours (24 hours if the child is aged 2 years or less).
- If your child requires antibiotics, paracetamol can be given at the same time, when required for fever and pain relief.

Published October 2012.

Appendix C: Participant Information Sheet

Participant Information Sheet

RO-15179

Title	**Making informed decisions about antibiotic use for coughs and colds in children**
Coordinating Principal Investigator/ Principal Investigator	*Professor Chris Del Mar, Associate Professor Tammy Hoffmann*
Associate Investigator(s)	*Mr Peter Coxeter*

Introduction

This Participant Information Sheet tells you about the research project. It explains what is involved in participating in the study. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

If you decide you want to take part in the research project, you will be asked to sign a Consent Form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

You will be given a copy of the Participant Information Sheet and Consent Form to keep.

What is the purpose of this research?

The research project is being conducted to compare two ways of presenting information to parents to better inform them about the evidence for antibiotic use for a child with an acute respiratory infection (for example, middle ear infection, sore throat, or acute cough). You are invited to take part in this research project, as you are the parent or primary caregiver of a child between 1 and 12 years of age.

This research in funded by the National Health and Medical Research Council, and the Australian Commission on the Safety and Quality in Health Care, and is being conducted by researchers at the Centre for Research in Evidence-Based Practice, Bond University.

What does participation in this research involve?
Your participation will involve:

- answering knowledge questions about antibiotic use for middle-ear infection, sore throat, or acute cough in children;
- reading an information summary;
- answering repeat knowledge questions about antibiotic use for use for middle-ear infection, sore throat, or acute cough in children;
- answering questions about your treatment preference if you were making a decision about a child's illness, and how confident you would feel in making this decision. We are also interested in how easy you felt it was to find and understand the information, and any comments you have about what you liked or did not like about the way the information was presented.

The questionnaire will take approximately 20 to 30 minutes to complete, and you may elect to complete the survey at a time more convenient for you.

You will be participating in a randomised controlled trial. We will be comparing two types of information summaries to see if one is better. To try to make sure the groups are the same, each participant is put into one of two groups by chance (random) and give each group a different information summary. The results will be compared to see if one is better.

There are no costs, or paid benefits or incentives, associated with participating in this research project.

Do I have to take part in this research project?
The survey has been approved by the Bond University Human Research Ethics Committee. Participation in this study is **completely voluntary** and you may withdraw at any time without risking any negative consequences. If you choose to withdraw your participation in this study, the information you have provided will be immediately destroyed. Data collected in this study will be treated with complete **confidentiality** and not made accessible to any person outside of the research team working on this project. Data released from the study will not include any information that can identify you to ensure you will remain **anonymous**. Data will be kept secure, password protected and stored in a secured location at Bond University for a period of 5 years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee.

What are the possible benefits of taking part?
There will be no clear benefit to you from your participation in this research. However, the outcomes of this research may benefit other parent's in the future by having access to the most effective information format when making decisions for acute respiratory illness in their children. This will enable parents to have greater involvement in health care decisions with their doctor about the best care.

Are there any risks from taking part?
The only foreseeable risk to you form taking part is inconvenience, and the time taken to fill out the questionnaire.

If you have any queries about the study or would like to be informed about the summary of research findings, please contact:

Appendix C (continued): Participant Information Sheet

Principle Investigator/ Supervisor
Professor Chris Del Mar
Telephone: (07) 559 52504
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Principle investigator/ Supervisor
Associate Prof. Tammy Hoffmann
Telephone: (07) 559 55522
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Co-investigator/Student
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Telephone: (07) 559 51588
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Address
Centre for Research in Evidence-Based Practice
Faculty of Health Sciences and Medicine
Bond University
Gold Coast, Queensland, 4229

Should you have any complaints concerning the manner in which this research (RO1744) is being conducted please make contact with –

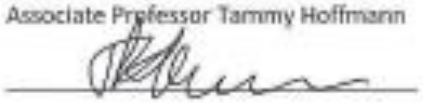
Senior Research Ethics Officer
Bond University Human Research Ethics Committee,
c/o Bond University Office of Research Services.
Bond University, Gold Coast, 4229
Tel: +61 7 5595 4194 Fax: +61 7 5595 1120 Email: buhrec@bond.edu.au

We thank you for taking the time to assist us with this research.

Yours sincerely,

Professor Chris Del Mar

Associate Professor Tammy Hoffmann



Mr Peter Coxeter

Chapter 8

Discussion

“One’s destination is never a place, but a new way of seeing things”

Henry Miller

Preamble to Chapter 8

This concluding chapter draws together key outcomes from the scoping literature review and each of the three original research studies. It discusses their contribution to the objective and aims of the thesis, elaborates on the strengths and limitations of each study, outlines the implications for clinical practice, and identifies opportunities for future research.

Safely reducing unnecessary antibiotic use for ARIs is a key strategy in the containment of antibiotic resistance and preservation of antibiotic effectiveness.[1] The objective of this thesis was to explore the appropriateness of using shared decision making to promote informed choice by parents as a strategy which may reduce antibiotic use for ARIs in primary care. A particular focus was on children, as they experience a higher prevalence of ARIs [2] and more frequently receive an antibiotic.[3] To explore the appropriateness of shared decision making, a systematic review and meta-analysis of studies established the effectiveness of interventions which facilitate it for decisions about antibiotics for ARIs in primary care (Study 1, Chapter 4);[4,5] a survey explored parents' beliefs and expectations about antibiotics for ARIs in children, and their preferred level of involvement in treatment decisions (Study 2, Chapter 5);[6] patient decision aids for three common ARIs were developed (Chapter 6),[5] and evaluated (Study 3, Chapter 7) [5] in a randomised trial to initially assess their effectiveness in preparing parents to make an informed choice about antibiotic use for a child's ARI in a hypothetic scenario, as a precursor to further evaluation in clinical practice. When considered together, the individual studies contribute knowledge about the potential of shared decision making as strategy for better managing antibiotic prescribing for ARIs, practical considerations for its implementation in clinical practice, and further research that is needed.

Summary of thesis findings

The problem of antibiotic resistance

The scoping of the antibiotic resistance literature in Chapter 2 provided an overview of the antibiotic resistance crisis and its evolution over several decades to emerge as a global threat to human health. The review identified international surveillance and stewardship efforts [7-11] in response to the WHO's call for strategies [1] to minimise antibiotic resistance. Australia's response to the emergence and spread of antibiotic resistance was the focus of the editorial presented in Chapter 3,[12] and the disjointed evolution of different bodies and responses and lack of an over-arching national framework was highlighted. Since publication of the editorial in Chapter 3,[12] the Australian Commonwealth Government has established a high-level steering group to provide leadership and accelerate state and national efforts to address the antibiotic resistance challenge, and an advisory group to provide expert advice on the implementation of national strategies, emerging issues and research priorities has been formed.[13] Australia's new Antimicrobial Use and Resistance in Australia (AURA) Surveillance System is a critical component of Australia's National Antimicrobial Resistance Strategy, and the first report [14] sets

out a national benchmark for monitoring resistance trends over time, and the early detection and rapid response to emerging issues. Previous initiatives have predominantly focused on hospitals, where the impact of antibiotic resistance is most evident, despite the majority of antibiotics being prescribed in the community [1,15] for conditions such as ARIs where they are usually unnecessary.[16] Several international programs have demonstrated that reducing antibiotic use can reverse resistance,[7,17-20] and this is therefore an important way of conserving antibiotics for more serious conditions. Hence, finding strategies that can safely reduce antibiotic prescribing in primary care, particularly for ARIs, is an important research objective.

Acute respiratory infections

The literature review presented in Chapter 2 highlighted the high quality evidence that shows how antibiotics are minimally effective in reducing symptom duration for common ARIs,[21-23] and that the benefit is often balanced with the risk of common harms,[24] as well as the risk of antibiotic resistance.[25,26] Several non-clinical factors that strongly influence antibiotic prescribing for ARIs in primary care were reported. Those that influence antibiotic prescribing for adults and children in primary care, and may be modifiable, included a clinician's desire to: do something to help 'just in case';[27,28] manage the consultation length and a way of concluding a consultation;[28,29] and achieve patient satisfaction and preserve the clinician-patient relationship.[30,31] Intertwined with many of these factors are patient (or parent) expectations for antibiotics, which may be inaccurately perceived by clinicians and not explicitly discussed or articulated in any way.[28,30] Prescribing antibiotics for uncomplicated ARIs also 'medicalises' otherwise self-limiting illnesses, and encourage patients to re-consult with similar treatment expectations in the future.[32]

Strategies addressing antibiotic use that can be used by clinicians in primary care

Of the available interventions that may reduce antibiotic use in primary care, regulatory measures are likely to be unpopular with prescribers, and externally administered educational interventions, guideline development, or clinical reminders, have individually been only modestly effective.[33,34] NPS MedicineWise has supported clinicians through various online training modules and resources, although their effect on prescribing outcomes has not yet been evaluated. The passive provision of patient education materials appears to have limited efficacy,[35] with interventions that focus on communication between patients and doctors possibly more effective.[36] Of the promising interventions that can be implemented individually

by clinicians, some have been evaluated in a number of trials and reviews (such as delayed prescribing[37]), whereas others need further research (such as behavioural nudge techniques [38] and shared decision making).

Interventions which aimed to facilitate shared decision making reduced short-term antibiotic use for ARIs in primary care

The Cochrane systematic review (Study 1) [4] assessed the effectiveness of interventions aimed at facilitating shared decision making about antibiotic prescribing for ARIs in primary care. The review included ten published reports of nine original randomised trials (one report was a long-term follow-up of the original trial) in over 1100 primary care doctors and around 492,000 patients. Key findings of the review were that, compared with usual care, there was moderate quality evidence that interventions which aimed to facilitate shared decision making reduced antibiotic prescribing for ARIs in primary care from 47% to 29% (RR 0.61, 95%CI 0.55 to 0.68) in the short term (immediately after or within six weeks of the consultations). There were insufficient data to assess whether the antibiotic reduction was sustained, or if there was improvement in the occurrence of shared decision making. No studies measured antibiotic resistance as an outcome.

The antibiotic reduction occurred without increase in adverse clinical outcomes, such as patient initiated re-consultations for the same illness, or decrease in patient satisfaction with the consultation, although the evidence for this is less certain. There were insufficient data to determine whether there was an increase in hospital admission, incidence of pneumonia, or mortality. Interventions were predominately aimed at developing clinicians' communication skills to facilitate shared decision making. Interventions which were aimed at engaging patients in the conversation were identified as an important area for further research.

Parents have misperceptions about the necessity, benefits, and harms of antibiotics for ARIs in children and desire more involvement in health decisions

The nation-wide cross-sectional survey (Study 2),[6] focused on childhood ARIs, because they are both common[2] and commonly treated with antibiotics,[3,39,40] explored parents' beliefs about these, quantified parents' expectations of antibiotic benefit, explored other management strategies they use, and described experience with and preferences for shared decision making. Most parents believed antibiotics are needed for common ARIs in children (particularly for AOM), and had many misperceptions about why they are needed and how they can help.

Parents grossly over-estimated (by 5-10 times) the benefits of antibiotics use on reducing illness duration compared with reductions in illness duration measured in systematic reviews of randomised trials. Most parents also believed that antibiotics reduce the likelihood of illness-related complications. Many parents were aware of potential harms from antibiotics (although they had some inaccuracies in knowledge about harms compared with clinical evidence).

Many parents were aware of the potential of antibiotic resistance, although some could not articulate the mechanism through which antibiotic resistance occurs or consequences of it. During the most recent visit to a doctor for their child with an ARI, slightly less than half (44%) of parents recalled at least some discussion about why antibiotics might be used. However, 72% reported little or no discussion about why antibiotics might not be used, and 78% did not remember any discussion about possible antibiotic harms. Nearly all (93%) preferred more involvement in future decisions about antibiotic use for their child's ARI.

Brief patient decision aids were acceptable to parents and enabled them to make an informed choice about antibiotic use for childhood ARIs in a hypothetical situation

With the eventual goal of facilitating shared decision making about antibiotic use for ARIs in children, Chapter 6 described the development of three brief decision aids to help patients/parents make an informed choice about antibiotic use for common ARIs (acute otitis media, acute sore throat, and acute bronchitis). Chapter 7 described Study 3,[5] a randomised trial which evaluated the decision aids in a community sample of parents, using a hypothetical future illness episode. The trial found that compared to the best written information currently available to the Australian public, the decision aids significantly improved informed choice, and parents' knowledge about antibiotic use in childhood ARIs (both conceptual and numerical risk perception accuracy), and enabled more parents to make an informed choice about whether to use an antibiotic for a child with a hypothetical future illness episode. However, the decision aids did not alter parents' attitudes towards antibiotic use, or intention to use antibiotics when their child has an ARI in the future. Parents liked the format and length of the decision aids, and their balanced content and visual presentation of antibiotic benefits and harms.

Strengths and limitations of the studies in this thesis

Although the strengths and limitations of the studies in this thesis have been discussed in the preceding chapters, they are summarised below (Table 10).

Table 10: Strengths and limitations of original research studies in this thesis

	Strengths	Limitations
Study 1 (Chapter 4)	○ Prospectively published review protocol ○ Rigorous adherence to review methodological standards ○ Comprehensive search strategy, with no year or language restrictions ○ Systematic identification and assessment of intervention details ○ Intervention details of included studies described in detail	○ Substantial heterogeneity in pooled outcome in the primary and key secondary outcomes ○ Meta-analyses could not be conducted for some clinically important outcomes
Study 2 (Chapter 5)	○ Australia-wide representative sample with 401 participants ○ Piloting and iterative development of questionnaire ○ Novel questions to quantify parents' expectations about antibiotic benefit on illness duration	○ Telephone landline-only sampling frame ○ Modest response rate ○ Some limitations in generalisability ○ Recall bias possible in some questions
Study 3 (Chapters 6 and 7)	○ Decision aids systematically developed using multi-stage approach recommended by international standards ○ Rigorous study design (randomised trial) and conduct ○ No loss to follow-up	○ Hypothetical scenario, as participants not facing an actual decision about antibiotic use at the time of the trial

Strengths

There are important strengths of the research projects conducted as part of this thesis. The Cochrane systematic review (Study 1) [4] included a published review protocol to protect against *post hoc* biases, and used a comprehensive and systematic approach to the search for eligible trials, formal assessment of the risk of bias, and grading of the quality of evidence. The

TIDieR [41] checklist was used to systematically identify and assess individual components of multifaceted interventions to evaluate their effectiveness and feasibility for adoption in Australian primary care. The national cross-sectional survey of parents' experiences and expectations about antibiotic use for childhood ARIs (Study 2) [6] involved a large sample, the questionnaire was developed iteratively and piloted, and included novel questions which quantified parents' expectations of the benefits of antibiotics. The evaluation of the brief patient decision aids for common ARIs (Study 3) [5] used a randomised trial design and was designed and conducted in a manner which minimised bias.

Limitations

There are several limitations inherent in each of the research projects presented in the preceding chapters. Findings of the Cochrane systematic review (Study 1) [4] may have limited generalisability to low and middle-income countries, and different cultural and healthcare settings. There were only several trials that included adults and children, and only one where children were the target population. Effect estimates were inconsistently reported for the primary outcome, and limited the number of studies included in each comparison. Similarly, there were too few studies to perform meta-analysis for several clinically important secondary outcomes, conduct a sensitivity analysis to formally assess the effects of trial quality (high versus low), or investigate observed heterogeneity in the primary and key secondary outcomes. Interventions included in studies varied widely in their scope, theoretical basis, components, mode of delivery, and duration. Intervention fidelity was not reported in most trials and the extent to which shared decision making actually occurred was not examined in any trial.

Limitations of the cross-sectional survey (Study 2) [6] include a landline-only sample, and modest response rate, both of which risk sampling bias: participants in the sample were disproportionately female, and with a higher level of education than the general Australian population. Recall bias may have distorted questions about the most recent visit to the doctor. Not all parents provided responses to all open-ended questions.

The randomised trial of the decision aids (Study 3) [5] asked parents only about a hypothetical future illness which may have generated different responses to if the questions were asked at a time when parents had a sick child and were facing the decision about antibiotic use. Administering the post-test questionnaire immediately after reading the allocated information may have overestimated participants' estimates of risk probability, and, ideally, a questionnaire administered later could have tested if responses were stable over time.

Implication of the thesis findings

Key implications for clinical practice and for future research, of the research that was conducted as part of this thesis are discussed below.

Implications for the format, content and use of an intervention to facilitate shared decision making interventions in Australian primary care

The systematic review (Study 1) [4] showed that most shared decision making interventions in this area, in accordance with accepted evaluation [42] and reporting [41] guidelines, are complex, multi-component and of quite high intensity (eg. five online training phases and outreach seminars; outreach visits and peer review of consultations). Consequently, they would be difficult and expensive to implement with clinicians outside of a research context. To be feasible in Australian primary care and able to be implemented in a widespread and sustainable manner, any intervention that aims to facilitate shared decision making needs to be simple, brief, and require minimal time commitments for training or use. A further challenge in developing an evidence-base for interventions when complex interventions are tested is the unknown contribution of individual components to overall intervention effects. Hence, while the systematic review demonstrated this type of intervention was effective, the minimal intensity and components that an intervention can have yet still be effective is unknown.

Parents' beliefs and expectations about the benefits and harms of antibiotic use for common ARIs, reported in Study 2,[6] informed the development of some of the content of the patient decision aids. The decision aids were designed to address the over-estimate of benefits and the under-recognition of the harms of antibiotic use for ARIs by presenting both the benefits and harms (along with the absolute risk of them), and doing so side-by-side, to assist patients to consider both during the conversation with their clinician. The aids should help to address the gap noted in Study 2, with parents rarely recalling discussing the benefits and harms of antibiotic use with their clinicians, or the option of not using antibiotics. Many parents expressed a preference for having discussions that covered this information. The aids also outlined what antibiotic resistance is and consequences of it, in response to the confusion about resistance that was identified in Study 2.

Implications for clinical practice

Study 1 [4] demonstrated that shared decision making is an effective strategy for reducing antibiotic prescribing for ARIs, notwithstanding the current lack of evidence to determine whether the effect is sustained. Consultations for ARIs and clinician-patient communication are likely to be enhanced by incorporating shared decision making techniques. Clinicians could also adopt other strategies, such as delayed prescribing, to assist antibiotic reduction, in conjunction with shared decision making. Knowing, from Study 2,[5] that most parents want to be involved in treatment decisions may facilitate clinicians' desire to offer shared decision making.

Inaccurate beliefs about the need for antibiotics and over-estimates of their benefits are likely contributors to explicit requests for them.[43] As the benefits and harms of using antibiotics are discussed during the process of shared decision making, this is an opportunity to correct misperceptions that patients/parents may have about antibiotic benefits and harms. It also suggests the importance of clinicians carefully eliciting the expectations of patients/parents in the consultation.[44,45] For example, if a parent states that they are expecting, or wanting, to receive antibiotics for their child's illness, exploring why they have that expectation may reveal beliefs about the necessity of antibiotics or concerns about consequences if antibiotics are not used. These beliefs and concerns can subsequently be discussed by the clinician, and correction and reassurance provided as needed. Qualitative research has revealed that clinicians typically do not ask direct questions about antibiotic expectations as they worry about creating an uncomfortable situation if patients are expecting them.[46] Using shared decision making strategies to have a conversation about the options of using and not using antibiotics, the benefits and harms of both options, and the patient's preferences and concerns may be a way to counter this reluctance.

Implications for research

As new trials of shared decision making interventions for decisions about antibiotics for ARIs are conducted, they should be incorporated into the Cochrane systematic review as an update. This may improve, in particular, the precision of the effect estimate on antibiotic prescribing rates. Trials which measure the effect on antibiotic prescribing in the medium to long term, and provide key secondary clinical endpoints (such as hospital admission, incidence of pneumonia and mortality) and process measures of patient or clinician involvement in shared

decision making would be most welcome. Future trials should also include a complete description of the intervention (such as by using the items on the TIDieR checklist [41]) to help systematic reviewers to synthesise interventions appropriately [47] and to aid the implementation of effective interventions into practice. Trials should also include assessments of intervention fidelity.

Further research is required to clarify the core competencies of shared decision making for clinicians. The extent to which clinicians need to receive training in using decision aids is unknown. It is generally accepted that training in shared decision making skills is essential, yet these opportunities are currently limited in Australia (including opportunities for student clinicians).[48] Clinicians often have inaccurate knowledge about the benefits and harms of interventions, and like patients, tend to overestimate the benefits and underestimate the harms.[49] Providing evidence-based information about the quantitative benefits and harms of interventions through brief decision support tools, such as decision aids, may also be a method of helping clinicians to know this information and should be explored.

The optimal way of communicating information about the potential harm of antibiotic resistance to patients needs further research, along with how patients consider this during decision making. For example, it is unclear whether patients weigh marginal treatment benefits against the societal consequences of antibiotic resistance (the so-called 'tragedy of the commons [50]). There is also likely the need to adapt tools that help facilitate shared decisions for patients from vulnerable populations,[51] such as those with very poor or marginal health literacy (estimated at over half of Australians[51]), or from non-Western cultural backgrounds who primarily speak a language other than English, and may not have adequate skills to engage in collaborative treatment decision with their doctor.

Finally, the developed decision aids need to be evaluated in a randomised trial in primary care with patients/parents who are facing a decision about antibiotic use for an ARI at that time. Also needed is further evaluation of the usability and acceptability of the decision aids to clinicians, their preferences for decision aid formats (for example, in hard copy or electronically) and how they are integrated into the flow of consultations, and how to measure the use of shared decision making in primary care consultations so that its adoption can be monitored. Whether antibiotic prescribing rates for ARIs reduce as a result of decision aids being used, and the effect that any reduction in prescribing has on local levels of resistance are also crucial questions that need to be explored.

Conclusion

ARIs, particularly during childhood, are one of the most common reasons for consultations in primary care and for the prescriptions of antibiotics. Clinicians often prescribe antibiotics despite strong evidence of marginal benefit and common harms, including antibiotic resistance which is now a global public health crisis. Inappropriate antibiotic prescribing is strongly influenced by potentially modifiable clinical and non-clinical factors, such as diagnostic uncertainty, perceived and articulated patient expectations for an antibiotic, and preservation of patient satisfaction. Overestimation of antibiotic benefits and poor understanding of their harms are likely contributors to the unnecessary use of antibiotics for ARIs. These misperceptions and the balance between the benefits and harms of antibiotics highlights the need to improve clinician and patient communication during consultations about these preference-sensitive decisions. Shared decision making appears to be an effective and appropriate strategy for improving informed choice about antibiotic use and an approach that is desired by patients. Decision aids are a tool that can be used to facilitate the process of shared decision making and enable better quality clinician-patient conversations. This thesis has explored the appropriateness of shared decision making as a strategy for improving the appropriateness of antibiotic prescribing for ARIs in primary care. The research conducted as part of this thesis has answered a number of previously unknown questions and may lead to the safe reduction of antibiotic prescribing for ARIs in primary care, and minimise resistance generation - one conversation at a time.

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